HCFA Master Contract
HCFA-95-023/PK

500

"Assessment of the Impact of Pharmacy Benefit Managers"

Project Officer
Kathleen Gondek, Ph.D.

David H. Kreling, Ph.D.
Co-Principal Investigator
University of Wisconsin, Madison

Helene Levens Lipton, Ph.D.
Co-Principal Investigator
University of California, San Francisco

Ted Collins, R.Ph.
Researcher
University of Wisconsin, Madison

Karen C. Hertz, M.A.
Research Associate
University of California, San Francisco

Center for Health Systems Research and Analysis
University of Wisconsin, Madison

Institute for Health Policy Studies
University of California, San Francisco

September 30, 1996

TABLE OF CONTENTS

Page

Page

ACKNOWLEDGEMENTS

Many people contributed to the successful implementation of the HCFA PBM study. In particular, the researchers would like to thank the many people in the pharmaceutical/ pharmacy field who generously shared their perspectives and insights with the research teams during interviews and site visits. Special thanks are due to the individuals listed below, who served as consultants, provided contacts, reviewed interview protocols, and responded to interim and final reports. In thanking these individuals for their varied contributions, we would nonetheless emphasize that the authors of the final report are responsible for any conclusions reached about pharmacy benefit management companies.

Administrative support was provided by Patricia Coray at the Institute for Health Policy Studies, UCSF, and Patricia Beutel at the University of Wisconsin, Madison.

Expert Panel:

Deborah A. Freund, Ph.D.
Indiana University

Mary Anne Kimble, Pharm.D.
University of California, San Francisco

Harold S. Luft, Ph.D.
University of California, San Francisco

Stephen W. Schondelmeyer, Pharm.D.
University of Minnesota

David G. Schulke
American Pharmaceutical Association
Washington, DC

Consultants/Reviewers:

Kathryn S. Duke, J.D.
University of California, San Francisco

Lynn Etheredge
Chevy Chase, MD

Robert C. Johnson
R. C. Johnson Associates
Scottsdale, AZ

Eleanor M. Perfetto, R.Ph., Ph.D.
Wyeth-Ayerst Research
Radnor, PA

John T. Skhal, Pharm.D.
Pharmaceutical Care Network
Sacramento, CA

Leslie Wilson , Ph.D.
University of California, San Francisco

Patricia Wilson
Associates and Wilson
Rosemont, PA

EXECUTIVE SUMMARY

Introduction

Pharmacy Benefit Management (PBM) companies are organizations which apply managed care principles to prescription drug programs with a goal of optimal and cost-effective drug prescribing and use. The PBM industry has experienced considerable growth because it has furnished clients with administrative efficiencies and drug program savings via retail pharmacy contracts that provide discounts on drug prices and dispensing fees, manufacturer rebates, increased generic substitution and drug utilization review. The industry also has grown because purchasers increasingly are becoming aware that drug therapy often presents a less costly alternative to other medical care, such as physician visits, hospitalization, emergency department use, etc. Payers have identified improved physician prescribing and appropriate patient drug use and compliance as methods to control costs (and hopefully improve quality), and they believe that PBMs will achieve these goals.

PBMs also are of interest because the industry is dynamic. In 1993 and 1994, the pharmaceutical market was jolted by the purchase by major pharmaceutical manufacturers of the three largest PBMs (PCS, Medco, and DPS). Manufacturers believed that vertical integration through ownership or alliance with a PBM would allow access to distribution channels, clinical databases, and information technology systems. Purchase of PBMs by manufacturers triggered a series of reactions by other stakeholder groups.

There has been very little systematic, empirical research of the organization, scope of services, types of clients and impact of PBMs on cost, quality, and the larger pharmaceutical market. This study was designed to provide more information on each of these areas and to provide a foundation for future large-scale, quantitative studies.

Research Questions and Methods

The research project was designed to focus on four issues:

1. Characterizing PBMs based on a literature review and developing a typology of PBMs from their characteristics.

2. Interviews with PBMs and stakeholders to develop a comparison of costs and quality of care in providing pharmacy benefits in Medicaid programs under OBRA '90 vs PBMs for privately insured or Medicaid enrollees in managed care.[1]

3. An analysis of potential impacts of PBMs on Medicaid and other government programs; including states' interest in direct contracting with PBMs; and issues raised by PBMs.

4. An analysis of the potential effects of PBMs on the larger pharmaceutical market including, but not limited to, pharmacies and pharmacists, pharmaceutical manufacturers, health benefits consultants, wholesalers, physicians, and patients.

PBM Characterization: Literature Review and Typology

PBMs administer and manage prescription drug programs for a variety of clients. The definition of PBM varies from a broad definition referring to firms which primarily perform claims processing and adjudication, to a more narrow definition which includes only "full-service" PBMs offering administrative services and clinical management of the pharmacy benefit. The "world of PBMs" is characterized by complex relationships among a variety of stakeholders including but not limited to purchasers, payers, providers, patients, and policy makers.

Activities performed by PBMs can be categorized into two main groups, administrative functions and drug use control activities. Administrative functions include selecting and maintaining a network of retail pharmacy providers, providing claims processing and adjudication, benefit design, record keeping and program reporting. Drug use control functions include policies and programs to affect drug use targeted towards pharmacists, patients, and prescribers such as formulary development and management, drug utilization review (DUR), disease management, and patient compliance programs.

Typology of PBMs

To characterize the universe of PBMs, a typology was derived from three primary sources of information -- directories in the May 1995 and 1996 issues of *Managed HealthCare*, a directory in the April 3, 1995 issue of *Business Insurance*, and a list of PBMs obtained from the American Pharmaceutical Association (APhA). A total of 107 PBMs were identified, and data for at least some characteristics were available for 89 PBMs.

---

[1] The Omnibus Reconciliation Act of 1990 (OBRA '90) mandates that state Medicaid programs implement prospective and retrospective DUR programs; drug counseling by community pharmacists for Medicaid patients; and rebates from drug manufacturers to all Medicaid programs for their products to be eligible for Federal reimbursement. In exchange for the rebate agreement, States were required to eiminate restrictive formularies.

Geographically, PBM headquarters are dispersed throughout the nation. Most PBMs listed their service area as "national," which may reflect their service area capabilities, rather than their actual client distribution. Many PBMs reported origins in managed care, pharmacy benefit administration, retail pharmacies, third-party administrators, insurance companies, and prescription mail order firms. PBMs often have developed from organizations for whom claims processing is a primary function.

PBM size can be measured in terms of number of covered lives or number of prescriptions managed per year. Double counting of covered lives occurs when multiple PBMs provide different services to the same group of people. Based on PBM-reported data in the directories, a dozen PBMs serve more than 10 million covered lives each, 6 PBMs have between 5 and 10 million covered lives, and the remaining 71 PBMs have fewer than 5 million.

Most PBMs reported providing a comprehensive set of services for clients. Over 90 percent of PBMs reported claims processing, maintaining a pharmacy network, prospective and retrospective DUR, and mail order prescription services.

Categorizing the PBMs by ownership type revealed that 4 manufacturer-owned PBMs have the largest number of covered lives, followed by 8 PBM-owned and 6 MCO-owned PBMs. A total of 23 PBMs were owned by pharmacy retailers.

PBM And Stakeholder Interview Findings

To characterize PBMs and study their impact, the research team used a case study methodology. The study was conducted over a fourteen-month period (July, 1995 through August, 1996). Data were collected from PBMs via site visits and from other stakeholders (i.e., PBM clients, pharmacy consultants at state Medicaid programs, health benefits consultants, and representatives from the retail pharmacy and pharmaceutical manufacturing industries) via in-depth telephone interviews.

Eight PBMs were approached and agreed to participate in the study, but due to logistical difficulties, a case study of one PBM could not be conducted. The seven PBMs studied represented variability in size, origin, geographic region and ownership status. Variation along other dimensions, such as PBM origin and number of Medicaid enrollees, was achieved without using these characteristics as selection criteria. Although the PBMs were not chosen randomly, they represent a large proportion of PBM covered lives.

Similarly, non-random, purposive sampling of PBM clients was employed to achieve a variety in client perspectives. A total of ten clients were interviewed, four employers and six MCO/insurers. The sampling included a mix of study PBM clients, clients who recently changed PBMs, or clients with Medicaid recipients in their populations.

Standard interview protocols were used to assess the commonalties and the range of variation in the characteristics of the PBMs, the clinical and administrative functions they perform, the dynamics of change they experience, their similarities and differences from the Medicaid program, and the assessments of respondents reports of the effects of PBMs on cost savings and quality improvement. These same topic areas were analyzed across the ten PBM clients.

Interview Findings

The interviews were designed to yield a comprehensive description of the administrative and drug use control functions PBMs perform, supported by relevant literature. From these data, the impact of the functions on cost and quality of care were derived.

PBM Administrative Functions:

Benefit Structure and Design

Included within PBMs' drug benefit structure and design are issues regarding specific drugs that are covered, limits on drug coverage, and patient cost-sharing requirements. The structure and design of the pharmacy benefit have critical influences on the costs of pharmacy care. PBMs can provide a standard benefit package for clients to adopt (based on typical packages used by other clients), or they can customize benefit packages to meet individual client needs.

PBMs reported that co-payments are the most common cost sharing approach used by clients, although there is an emerging trend toward co-insurance. Often, these cost sharing provisions are adjusted to facilitate or enhance drug use management initiatives implemented by PBMs. For example, differential co-payment amounts can be used for formulary preferred or generic drugs to direct patient demand to lower-cost agents.

Pharmacy Network

PBMs typically rely on community pharmacies primarily and mail service pharmacies secondarily to provide prescriptions to clients' drug program beneficiaries. Pharmacies contract with PBM to serve as the PBM's provider panel or network. These contracts ensure PBM-covered drug program individuals will have access to pharmacies, and vice versa.

Since PBMs can represent considerable numbers of patients to a pharmacy, traditional price-volume trade-off can be present in payment offers or negotiations PBMs have with pharmacies. If PBM contracts can be restricted to limited numbers of providers, additional discounted prices may be obtained from those participating providers.

However, in 31 states there are legislative barriers in the form of "any willing provider" laws that can constrain PBMs from attaining possible price-volume trade-offs that markets may allow.

Responses from the PBM interviews were:

- All PBMs have broad "national" networks with greatest patient access to providers, highest pharmacy reimbursement rates, and fewer drug use management and performance parameters.

- Network pharmacies have minimal participation requirements (e.g., current license, compliance with reimbursement rules, maintenance of prescription records, charge required co-payments)

- Typical contract terms are one to two years.

- Strategies for choosing participants vary; restrictive panels often focus on first attaining a chain pharmacy base and extending to independent pharmacies as needed for coverage.

Mail Order Services[2]

All surveyed PBMs included mail order services as an option. Mail order is viewed as a standard component in the PBM industry, although varying levels of emphasis are placed on mail order services by different PBMs. Three of the PBMs interviewed recently acquired mail order firms or were building their own facilities to incorporate mail order as an "in-house" capability. The reasons for these acquisitions included increased consumer/employer demands, ability to provide standardized pharmacist training for patient or physician interventions, presence of supervisory personnel and resultant pharmacist accountability, and effectiveness and efficiency in drug management efforts. One PBM reported twice the success rate for switches initiated by mail service pharmacists compared to the retail network. PBM clients' opinions on mail order service ranged from enthusiastic to pessimistic. Differing views were expressed about mail service's acceptability to members, and its potential to achieve drug cost savings.

PBM Charges to Clients/Financial Arrangements

PBMs reported using a variety of mechanisms for charging clients for their services. The most common mechanism is an administrative fee (or "transaction fee") charged per prescription claim. Typically, this "base rate" does not include clinical services such as disease management. Additional fees -- on a per covered life, per member

[2]Some analysts regard mail order as a part of the PBM benefit design (administrative function), while others regard it as a professional/provider set of activities that serve a drug use control function. In the subsequent discussion, the former view has been adopted.

per month (PMPM), or "lump sum" per month basis -- may be charged for retrospective DUR, disease management, or pharmacist formulary compliance incentive programs.

Risk-sharing arrangements, particularly capitation, are not common but are gaining momentum. It was reported that some PBMs with capitated contracts have experienced financial losses, and PBMs have mixed feelings about capitation. Shared risk arrangements (e.g., for a PMPM risk corridor with savings/loss sharing) may be more acceptable than capitation and have stimulated significant client interest. More commonly, a PBM might respond to client requests for "guaranteed savings" with regard to levels of formulary compliance, achievement of targeted generic dispensing rates, etc. In this case, the PBM is at risk in terms of achieving the promised level of savings. A challenge arises in determining how these savings should measured. For example, a methodology for assessing change in costs relative to a certain baseline measurement must be established. PBMs also offer guarantees on a number of "customer service" parameters (e.g., average waiting time for customer service calls) and custom-design these guarantees in response to client requests.

Some PBM clients reported that they are unwilling to capitate PBMs, largely because they believe that capitation would result in loss of their control over major decisions and information flow, as well as a loss of patient choice. Some clients asserted that capitating PBMs could result in greater overall medical costs. If PBMs were capitated, it would encourage them to use the lowest-cost drugs to come in under the capitation rate, potentially resulting in higher overall medical care expenditures due to use of sub optimal therapies. Most clients reported a preference for shared-risk arrangements and performance guarantees.

PBM Drug Use Control Functions:

Formulary and formulary-related activities

Developing and maintaining formularies are major functions performed by PBMs. Formularies provide the overarching structure for the drug benefit because they define which drugs can be prescribed and used. Specific PBM drug management activities occur within this overarching structure (e.g., prior authorization, therapeutic interchange, disease management). There are three types of formularies: an open formulary includes all drugs and drug products; a closed (restricted) formulary is a limited list of drugs approved for use or covered under the drug plan; and a "managed" formulary is a basically an open formulary containing "preferred" drug products as well as incentives and interventions to encourage use of these products by physicians, pharmacists, and patients.

PBMs were questioned about the different types of formularies they used, the processes by which formularies are developed and compliance is encouraged, and their assessments of the value of formularies.

Most PBM covered lives -- ranging from 80 to 100 percent -- receive some type of formulary management services. Smaller PBMs may contract out formulary services (e.g., to other PBMs specializing in formulary management). However, many PBMs have their own independent P&T committees which develop and update the formulary at quarterly intervals and provide input into other clinical areas (i.e., the development of disease management programs). Some PBMs noted that the P&T committee considers drug cost in making formulary decisions, but in one PBM the committee considers only clinical issues. Another PBM stated that it did not bring rebate arrangements into formulary development, whereas others made such considerations explicit. Large, sophisticated clients are more likely than other types of clients to request modifications to the PBM-designed formulary.

PBMs and their clients are encouraging providers to prescribe and dispense formulary products with a variety of mechanisms from education to financial incentives, but aggressive formulary enforcement is relatively rare among most PBMs. The majority of PBM covered lives use an open formulary, particularly those in indemnity insurance and large employer-sponsored plans. However, interviewees mentioned a growing interest in managed and closed formularies and an emphasis on generic drugs. This trend is particularly evident among PBMs' managed care clients. The number of PBM covered lives on a closed formulary remains relatively low, generally between 10 to 25 percent of total covered lives in the PBMs studied.

PBMs reported that changing physicians' prescribing practices is the key to success for PBMs' formulary management activities. Efforts to increase physician compliance to the formulary include written, telephone, and in-person communication from PBM staff and pharmacists about preferred drug products, educational materials mailed to patients who are urged to encourage their physicians to prescribe formulary products, and PBM-generated profiles of physicians' prescribing patterns which are mailed to physicians. Some MCOs have capitated physicians for drug costs or overall health care costs, or instituted "withholds" based on formulary compliance. According to PBMs, the assumption of risk for pharmacy utilization is a powerful incentive enhancing physicians' willingness to comply with formularies, and its prevalence may increase in the future.

To encourage formulary compliance by pharmacists, several PBMs stated that they had instituted financial incentives, such as "floating" dispensing fees based on formulary or generic dispensing performance within specific pharmacy networks. Some interviewees suggested that pharmacists' willingness to respond to such incentives is mitigated by other requirements and incentives created by PBMs, such as high volume dispensing and time-intensive documentation of drug interchanges.

At the patient level, formulary compliance is encouraged primarily through educational materials promoting preferred drug lists and financial incentives, such as lower co-payments or co-insurance for formulary or generic drugs.

Very little information is available about how PBMs measure success of formulary management interventions. Some PBMs considered this type of information proprietary, while others felt that aggregates of multiple clients' cost savings were not statistically meaningful. One PBM reported that a closed formulary could yield a savings of 4 - 8 percent for a client. An interviewee explained that PBMs have reduced drug costs for their clients by fostering competition within drug therapeutic classes, particularly with regard to "me too" drugs, thereby suppressing price increases. Other clients indicated that they believed aggressive formulary management slowed growth of per member per month (PMPM) costs. Several PBM clients commented that Medicaid programs would obtain better value in the long-term by increasingly managing their formularies. However, they noted that PBMs contracting with Medicaid MCOs often have little leverage with formulary management because they may be required to use the state formulary.

Interchange Programs: Generic Substitution and Therapeutic Interchange

As a method to encourage the use of cost-effective drugs, generic substitution is more common and less controversial than therapeutic interchange. All PBMs interviewed for this study offer their clients generic substitution programs or incentives for pharmacists or patients to use generics such as maximum allowable cost (MAC) programs, differential dispensing fees, "floating" dispensing fees based on pharmacy generic dispensing rates as compared to peer norms in the region, or differential patient co-payments for generic and brand name drugs. Two PBMs reported that they send letters to pharmacists reminding them about contractual obligations to meet certain generic dispensing standards, with penalties that include possible removal from the network.

Therapeutic interchange programs occur when a pharmacist in the PBM network or mail service pharmacy contacts a physician for approval of a switch in prescription, such as from a nonformulary to a formulary drug, when the new drug is chemically different from the originally prescribed drug but has a comparable therapeutic effect. A primary goal is to foster more appropriate drug therapy. Some PBMs also contact the patient to increase the success of the therapeutic interchange. Therapeutic interchange programs are often integral components of PBMs' efforts to increase formulary compliance and shift market share to rebated products. About half of the surveyed PBMs offer therapeutic interchange programs, including pharmacist reimbursement (see section on cognitive services), although several of these programs are relatively new. PBM clients may be required to pay extra charges for interchange programs implemented in the retail network.

A central feature of therapeutic interchange programs is telephone communication with the physician for approval of a switch in prescription. Some evidence indicates that PBM strategies in the retail sector are coalescing around physician calling programs. Increasingly, PBMs believe that physician calling is an effective approach to influencing prescribing behavior. Some interviewees believed that a primary advantage of mail order pharmacies is their ability to conduct interchange interventions more successfully than

retail pharmacists; they asserted that mail service pharmacists face fewer time pressures in contacting the prescribing physician, undergo training in communications skills, and have been educated about targeted disease states and drug therapeutic classes.

The primary goal of therapeutic interchange programs is to reduce drug costs and maintain rebates. It is difficult to assess if these programs have an impact (either positive or negative) on patient health outcomes and overall medical costs. Typically, data on cost savings achieved through interchange programs in terms of impact on total health care expenditures are unavailable.

Cognitive Services

PBMs typically used the term "cognitive services" to refer to pharmacists' actions in responding to on-line DUR messages at point-of-sale, such as contacting the physician about switching a patient's prescription, successfully obtaining approval for the switch, reversing a prescription, or modifying medication dosage, as well as counseling patients on their drug therapy.

About half of the surveyed PBMs are reimbursing pharmacies for cognitive services. In many cases, cognitive services reimbursement is still in the experimental stage. Cognitive services reimbursement may be offered only to those clients using restricted or performance-based pharmacy networks, if such exist, because pharmacists in these networks have been qualified to perform "special" services. Other PBMs expressed the view that they were able but unwilling to reimburse pharmacists for the provision of cognitive services.

Cognitive services are reimbursed at various levels depending on the type of intervention. Among the PBMs studied, the highest payment ranged from $7 to $15. Payment for cognitive services is made to the *pharmacy* -- attenuating the *pharmacists'* incentive to perform or document the provision of cognitive services. Some interviewees suggested that pharmacies could encourage performance and documentation of cognitive services with financial incentives for the employee pharmacists.

Drug utilization review (DUR)

Another drug use control function prevalent in PBM settings is drug utilization review (DUR), a structured, ongoing program that interprets patterns of drug use in relation to predetermined criteria and attempts to prevent or minimize inappropriate prescribing. DUR may be conducted retrospectively or prospectively, and OBRA '90 mandated both types.

Retrospective drug utilization review (R-DUR)

Most surveyed PBMs offer R-DUR programs. In many instances, it was difficult to determine the actual number of covered lives receiving R-DUR services under PBM benefit packages. Several PBMs reported that only a small proportion of their contracts included R-DUR, or that it was performed on a "case-by-case" basis for "larger clients." Other PBMs reported that from 70 to 100 percent of clients received R-DUR services.

Almost all PBMs performing R-DUR do so "in-house." Written correspondence with physicians is the most common intervention applied by PBMs. Letters include physician profiles with peer comparisons, patient profiles, and educational information on targeted drugs or disease states. In some cases, physician correspondence is conducted as part of new disease management initiatives. All PBMs reported that profiles of pharmacies are evaluated as part of R-DUR programs. Typically, these profiles are mailed to pharmacies and PBM clients on a quarterly basis.

Interviewees hypothesized that Medicaid programs may have an advantage compared to PBMs, in that they have access to medical claims data which can inform DUR interventions. Access to medical claims data also enables better evaluations of the DUR interventions' impact on quality and costs. In contrast, PBMs must obtain cooperation with clients for access to these data. One Medicaid expert interviewed believed that R-DUR programs provided by Medicaid and PBMs were, on average, equally competent. However, PBM's distribution of physician profiles may be effective tools in improving prescribing patterns.

Prospective drug utilization review (P-DUR)

With the exception of one PBM which "outsources" most claims processing and DUR activities, all interviewed PBMs provide in-house, on-line claims processing and P-DUR. All PBM covered lives on the claims processing platform typically receive P-DUR. PBM representatives stressed that on-line, point-of-service P-DUR programs represent a great advance in PBM capabilities and are a standard service provided in PBM programs. Several interviewees indicated that Medicaid programs that had not yet transferred administration of their pharmacy benefit to on-line systems would be wise to do so as quickly as possible.

A challenge with P-DUR systems is developing and employing criteria to screen for drug use problems that are specific and sensitive enough to enhance quality and flag potential drug use problems, yet not overload the system with "false positives." Also, typically, access to P-DUR is restricted to the pharmacy claims database, although several PBMs are incorporating medical claims data in collaboration with some of their most "proactive" large clients.

PBMs' abilities to track actions resulting from DUR alerts vary widely and allow for limited assessment of results of P-DUR programs. One PBM reported that a new

computer system permits DUR actions taken by pharmacists, while another is encouraging pharmacists to code reasons when a DUR alert is ignored. More typically, PBMs report limited information to clients, such as the total number of DUR alerts generated for their covered lives and the number of resulting denials or reversals. However, clients noted that the analysis of P-DUR programs was limited not only by PBM systems capacities, but also because PBM clients may not have staff pharmacists and data managers to analyze and react strategically to DUR reports.

A Medicaid expert reported that small states' Medicaid programs are less likely to have on-line P-DUR programs, stating that pharmacists in these states perform P-DUR at point-of-sale without the aid of on-line systems. However, large states have on-line P-DUR systems. Some Medicaid programs do not want to invest in on-line, point-of-sale systems because they are moving recipients into managed care plans which will manage the pharmacy benefit.

Disease Management

All surveyed PBMs were developing, piloting, or initiating disease management programs at the time of the site visits. Most programs were in various stages of pilot testing or being finalized for production, with one PBM reporting having programs in "full production." At present, disease management programs typically affect a very small percentage of PBMs' covered lives. Asthma, depression, gastrointestinal conditions and diabetes lead the list for PBM disease management initiatives, largely because improved compliance with self-management practices, prescriber adherence to best practices, and appropriate use of these medications can result in cost savings.

There is wide variation in how PBMs are paid for implementing disease management programs. The programs are not part of the typical package of services offered to most clients. Generally, if clients desire disease management services there are additional charges for these programs; however, several PBMs are piloting disease management programs as joint projects between the health plan and PBM as "beta testing" and the health plan does not pay for the program until the results are measured and proven. Some disease management services are provided on a risk-sharing basis. For example, even though the PBM charges its clients for these programs, it may provide savings guarantees, i.e., promises to clients that if these programs do not lower associated physician and hospital costs, then the PBM will lower its overall bill accordingly.

Reactions among PBM clients to disease management programs ranged from skepticism to cautious optimism. Concerns raised by clients were that PBMs over-promised what they could provide in the way of disease management services and that PBMs do not "deliver" minimal services (e.g., patient education).

Outcomes Assessment

About half the surveyed PBMs are assessing pharmaceutical therapy using clinical outcomes. Measurement of clinical outcomes appears largely restricted to client populations enrolled in new disease management programs and is occurring on a limited basis. At least one PBM is coordinating outcomes research efforts with its parent company, a major pharmaceutical manufacturer. Others are working in partnership with parent company subsidiaries which focus on disease management, information technology, or outcomes research.

PBMs are measuring a variety of outcomes measures, most of which are centered on "intermediate" patient outcomes, that is, laboratory results. Some PBMs are tracking emergency room, hospitalization and /or physician office visits as part of their new disease management programs, whereas others report that their clients perform these activities.

PBMs stated their intention to examine the clinical, economic and "humanistic" (quality-of-life) outcomes of their disease management initiatives, but in most cases PBMs assert that the disease management programs have not been implemented long enough to evaluate outcomes. A few PBMs are working with large clients (typically HMOs) to examine clinical outcomes, using data sets from the HMOs and the PBM.

Cost Savings in the PBM Environment

A major goal of PBMs is to achieve cost savings for their clients while maintaining or improving quality. Specific questions were posed to PBMs to gather information and their assessments of pharmacy payments, PMPM costs for a marketbasket of drugs, overall PMPM costs, rebates, and estimates of cost savings attributable to specific PBM functions.

PBMs answered these questions with varying degrees of specificity, and in some cases, not at all. Comparisons were made between PBMs and Medicaid programs where possible and appropriate.

Pharmacy payment formulas

PBMs have been aggressive with their payment terms to pharmacists for prescriptions, often establishing the deepest discounts in drug cost reimbursements and dispensing fees in market areas. A comparison with state Medicaid payment formulas shows PBMs generally have had higher discounts off AWP for ingredient cost reimbursement and lower dispensing fees. Typical PBM payments were AWP less 13 percent for ingredient costs and $2.50 dispensing fee, compared to a norm of AWP less 10 percent and an average $4.22 dispensing fee for state Medicaid programs. For multi-source drugs, PBMs and Medicaid, have Maximum Allowable Cost (MAC) programs.

Most PBMs reported their MAC programs were more aggressive than Medicaid MACs, likely yielding some additional savings when compared to Medicaid.

Costs for drugs/marketbasket of drugs

To describe possible differential cost savings across PBMs, PBMs were asked to provide PMPM costs, average prescription size and days supply for a marketbasket of 8 drug groups.[3] Most PBMs did not disclose this information because these data were considered proprietary and/or not readily retrievable. It appears these data are not part of standardized reports or monitoring information used by the PBMs. Only one PBM completed a cost matrix of PMPM costs for the marketbasket drugs, and the costs they reported were based on AWP. The resulting differences in PMPM costs reflected differences in patient groups and benefit designs that affect costs.

Thus, this market comparison did not prove useful, not only because of poor response rate, but also because of variation in the patient and drug use mixes generating the aggregate results. Although the comparative data were not available, this remains a valuable line of inquiry for purchasers to pursue.

Changes in costs PMPM

Changes in PMPM cost experienced by PBMs in recent years typically were in the range of 6 to 8 percent increases. Several PBM executives predicted double digit increases likely will be seen in the future. They remarked that "Easy cost savings have been squeezed out," referring to downward pressure on dispensing fees and decreased ingredient cost payments through larger percent discounts off AWP, and shifts to more generic dispensing. Additional reimbursement formula savings resulting from exclusive provider arrangements or restricted panels were considered more difficult cost-cutting strategies, given any willing provider legislation, increasing unwillingness of pharmacist providers to accept additional decreases in reimbursement, and employers' reluctance to restrict consumer access to pharmacies.

Other drug use management efforts to reduce costs may be more difficult for PBMs to initiate and/or control via centralized administrative and policy efforts. These other efforts, such as more restrictive formularies, aggressive therapeutic interchange and prior authorization programs, disease management, etc. require involvement and additional efforts not only by PBMs and provider pharmacists, but also by physicians, patients, and PBM clients.

---

[3] The selected drug classes included: histamine-2 receptor antagonists, nonsteroidal antiinflammatory drugs, antidepressants, oral contraceptives, ACE inhibitors, cholesterol reducers, cephalosporins, and calcium antagonists.

The PBMs attributed current costs trends to changes in the mix of drugs dispensed, increased utilization, and shifting of some drugs such as injectibles to the drug benefit from major medical coverage. PBM clients suggested cost increases were due to several factors, including drug price inflation, introduction of new, expensive drugs into the market, adverse selection, and inadequate monitoring of PBMs. Clients reported some success in controlling costs by hiring in-house pharmacists to monitor and enhance PBM efforts, and by more aggressive application of innovative PBM cost and drug use control techniques.

Contracts/Rebates

Rebates or contracts are perhaps the most controversial and sensitive PBM activity. Many of the complexities of PBMs, ranging from all aspects of drug use management to charges between clients and PBMs, can be related in some manner to rebates. Rebates also are of legal interest to pharmacists due to discriminatory pricing issues, and pharmaceutical manufacturers because of concerns about anti-competitive behaviors of manufacturer-owned PBMs.

Several PBMs quantified the amount of rebates they earned per claim and as a percent of "total drug spending."[4] These amounts varied among different clients. Clients with aggressive drug use management programs, such as managed formularies, could achieve higher rebates because the rebate levels often are linked to market share changes.

The available information indicates that on a per-claim basis, an overall estimate of rebate falls around $1.25. Typical amounts ranged between $1.00 and $1.50; specific plans reported amounts ranging from $0.80 to $2.50 (an exceptional case). As a percent of total drug spending, respondents' estimates hovered around 6 percent, again with variability across PBMs and among different clients using the same PBM.

A few PBMs also quantified approximate percent rebate levels, nominally and/or relative to OBRA '90 Medicaid rebates. These data revealed that PBMs achieve lower rebates and had less ability to extract rebates universally from manufacturers, especially generic firms, as compared to Medicaid agencies.

Some PBMs described how rebates they negotiate are passed on to clients. They may use rebates as part of their pricing/marketing strategies, in part because clients expect it. The rebate arrangements with clients are structured to "share" the rebate that PBMs negotiate with manufacturers, turning most of the rebate (the total less an "administrative" proportion) to the client. Interviews with clients revealed that there is considerable variability in the percent of rebate shared, ranging from 0 to 100 percent of rebate earned by the PBM.

---

[4] Total drug spending may be defined as drug costs plus fees less applicable co-payments.

Some respondents observed that there are two other types of "rebates" received by PBMs from pharmaceutical manufacturers, revenues received for sharing drug use information and funds received by the PBM for projects sponsored by manufacturers. Reimbursement for these activities may be based on a flat fee, a fixed amount per claim, or a percentage of drug costs.

Cost savings estimates

Interviewers asked PBMs specific questions about cost savings generated for their clients for performance of specific PBM functions. Limited quantifiable data were reported by PBMs because most considered these data proprietary. One PBM offered projected incremental savings for clinical management programs of 3 to 8 percent, closed formularies 4 to 8 percent, and prospective DUR programs 2 to 4 percent. Another estimated 4 to 5 percent savings from prospective DUR, while another PBM report indicated a 15 to 20 percent savings over major medical reimbursement.

PBMs reported that savings resulted from reduced pharmacist payment levels, patient co-payments, restricted or managed formularies and mail order services. One PBM noted that if a client demanded stringent savings guarantees or payment via capitation, the PBM would demand a managed or closed formulary. This statement suggests that major savings may be realized in these areas.

PBMs reported using historical comparisons for evaluating savings, typically using the onset of a contract as a baseline, but also incorporating comparisons with previous clients or the entire PBM business as benchmarks. Potential savings vary considerably based upon the client's baseline for comparison. For example, if a PBM has a new client that formerly had an indemnity prescription coverage plan, savings would be derived from different areas than if a new client was a managed care organization or a former client of a competitor PBM that had already instituted drug use and pharmacist payment control measures. Given the variations in clients' organizational structures and previous levels of drug plan management, it is extremely difficult to assess the nature and magnitude of savings across PBMs.

PBM Client Perspectives

Clients were interviewed because their strategies to control costs and improve quality have a major impact on the PBM industry and because their views give perspective in attempting to assess the impact of PBMs. Clients contract with PBMs for several reasons including the cost efficiencies inherent in using PBMs' computer system for claims processing and adjudication, periodic reports on drug utilization and expenditures which enable them to implement incentive programs for patients and pharmacists, PBM clout in negotiating rebates and other discounts with drug manufacturers and pharmacies. Although not all clients agreed, some asserted that hiring pharmacists is part of a general

strategy for bringing management of the clinical and other PBM services back into the health plan. Thus, some PBM clients believe that once they work with PBMs and "get up on the PBM learning curve," they can internalize certain PBM functions (particularly clinical services) and realize greater economies.

Clients that had switched PBMs offered several reasons for the changes. In some cases, PBMs were not performing certain clinical functions optimally or at all; in other instances, clinical functions performed by a PBM were not perceived by clients to be "state of the science" (e.g., DUR was not on-line, real time). Further, clients switched PBMs because in their view formulary decisions were based on rebates rather than on clinical information. (This concern was more likely to be expressed with regard to vertically integrated PBMs.) Finally, several clients observed that health benefits consultants contributed to firms changing PBMs.

Potential Impact and Roles of PBMs for Medicaid and Other Government Programs

Medicaid Consultant Perspectives

Telephone interviews with state Medicaid pharmacy consultants were completed to assess Medicaid interest in, and experience with, PBMs. We selected six states that we believed had interest or experience with direct contracting with a PBM, or that had a high number of Medicaid recipients enrolled in MCOs. None of the Medicaid programs have contracted directly with PBMs to manage their drug benefit. Most indicated there was a lack of data to support net savings over Medicaid administered programs.

States reported that PBMs potentially could reduce administrative costs, reduce political pressure on formulary decisions and pharmacy network restrictions, and if risk contracts with PBMs were arranged, it would permit the state to have a firm budget estimates.

Several potential barriers to contracting with a PBM for Medicaid drug programs were expressed. They included: 1) existing contracts to process claims would have to be re-negotiated; 2) HCFA waivers would have to be sought if states restricted beneficiary access to providers or limited service; 3) PBM denial of claims may result in many appeals to Medicaid; and 4) an inability to use co-payments to reduce drug costs in the same way PBMs use them in the private sector.

All pharmacy consultants mentioned a primary interest in their state was expanding the use of managed care organizations (MCOs) for Medicaid recipients. Two states reported carving the drug benefit out of the MCO contract and continuing to manage it themselves. In other states, the drug benefit was managed by PBMs via subcontracting with some of the MCOs. Three states required that contracts with managed care organizations pay no more for drugs than the net amount paid by Medicaid (paid amount

less rebates). The pharmacist consultants had little involvement in developing or monitoring drug therapy under managed care. Some consultants mentioned that MCOs use formularies to manage the drug benefit, an intervention not permitted by Medicaid regulation.

Potential Impact of PBMs on State Medicaid Programs

Pharmacy Payment

Relative to current Medicaid payment levels in many states, PBM reimbursements to pharmacies are lower, both in dispensing fees and EACs. Consequently, PBMs could be an economizing strategy for state Medicaid programs. If pharmacies respond by attempting to increase efficiency in prescription processing, quality of care may be adversely affected. To speed prescription processing pharmacists may reduce time spent evaluating therapies and drug use and decrease patient contact time.

Maximum Allowable Cost (MAC) Programs

The impact of PBMs on generic dispensing likely would be marginal compared to Medicaid programs and limited mainly to more rapid additions to MAC lists. Current state MAC programs provide high levels of generic dispensing for multi-source drugs. Generic substitutes are accepted relatively widely by prescribers and patients and any changes are not likely to impact quality.

Rebates

The rebate levels and number of products covered by rebates may be reduced if PBMs are chosen to manage State Medicaid programs. Based on HCFA rebate experience data (third quarter FY 1994-95 data), about 18 to 21 percent of Medicaid drug spending is rebated. PBM interview responses showed PBM rebates are considerably lower (about 6 percent of drug spending). In Medicaid, essentially all products are rebated, but PBMs' rebates are not as universal. Medicaid now receives all rebate dollars, but if PBMs administer the rebates, they likely will withhold a portion as "administrative fees."

Restricting the Panel of Pharmacies

PBMs may restrict the number of participating pharmacies to obtain price concessions from pharmacies in return for increased customer volume or to establish a performance-based network. These restrictive panels often have a $0.50 or more dispensing fee concession, and a higher percent discount off AWP for ingredient cost payment.

Restricted panels may reduce access to pharmacy services for some Medicaid recipients. However, if the panel is restricted to achieve enhanced pharmacy performance, quality of care may improve.

Mail Service Prescriptions

The level of savings resulting from mail service pharmacy is debatable. Mail service may provide enhanced switch rates to preferred drugs and yield savings that may accrue from directing use to those products. Special Medicaid concerns with widespread use of mail services include frequent eligibility changes, recipients who lack stable addresses where prescriptions can be sent, a possible potential for waste or fraud among Medicaid recipients, lack of incentives to direct patients to use mail service, and inappropriateness of Medicaid populations for mail service (AFDC recipients have more acute prescription drug needs, LTC recipients use unit dose distribution, and chronically mentally ill require more interaction with pharmacists). However, some populations, such as the elderly, may benefit from the convenience of mail service.

Formularies (and Formulary-Related Activities)

Formularies and formulary-related activities, such as prior authorization and therapeutic interchange, can help direct product use to "desirable" (based on cost or quality aspects) agents. Directing physicians, pharmacists, and patients to more cost-effective agents has potential for drug program and overall, long-term program savings. However, as a result of federal regulations, Medicaid recipients cannot be incentivized towards utilization of preferred drugs to the same extent as patients in private markets, e.g., via lower co-payments for preferred products. In the PBM environment, as in other settings, the implications of closed or managed formularies on quality of care and clinical outcomes are unknown.

When developing formularies, PBMs are more insulated from political pressures than are Medicaid programs. This may allow them to give priority to quality, as well as cost, when developing drug lists.

DUR (Prospective and Retrospective)

DUR programs (both prospective and retrospective) have potential for enhancing quality of care by improving patterns of drug use. Relative effectiveness of PBMs versus Medicaid capabilities and success in this area are not known. In many cases, the PBM provides R-DUR information to clients who then analyze and implement their own interventions based on PBM generated data.

All Medicaid programs operate retrospective DUR programs. Some of the same questions are relevant for prospective DUR, but unlike PBMs, not all state Medicaid programs have POS systems.

Disease management

Disease management is in preliminary phases only, although there is more movement and innovation on the private side than the public side. Problems integrating drug and medical data sets are present in both environments, although there may be more history and experience in Medicaid programs. A concern is whether disease management programs merely are veiled efforts to enhance the market share of drug firms that own PBMs.

Administrative Cost of Claims Processing

PBMs may be better equipped to achieve efficiencies and lower claims processing costs (charges). If prescription claims processing is shifted to PBMs, economies of scale may be reduced for other claims (e.g. medical) and the costs for these claims might increase (i.e. contractors would, in all likelihood, increase charges for processing these other claims).

Issues Raised by PBMs for Medicaid Programs

The following issues should be considered by States when considering contracting with PBMs for managing drug benefits. Medicaid populations have different medical needs from traditional PBM populations and contain large proportions of high cost patients. These populations more likely need services of specialists and may receive care from providers not commonly found in managed care networks. Long-term-care residents present a different challenge to PBMs not accustomed to managing institutional drug use. Many of the cost containment methods used by PBMs may not work with Medicaid populations. Mail order services may not save money if there are frequent changes in eligibility. PBM patient cost sharing incentives for formulary or preferred drugs are not transferable as Medicaid recipients have little discretionary income to spend on co-payments and non-formulary (i.e., non-covered) drugs. Restrictive provider panels may reduce access to recipients dependent on public transportation to visit pharmacies.

Unlike most PBM clients, Medicaid has years of experience in implementing and managing cost containment programs such as MAC, DUR, prior authorization, provider audit/utilization review. State Medicaid programs have internal pharmacist consultants with experience in claims processing and utilization review. Medicaid, as a public program, is subject to greater political pressures, greater public access to policies and information than typical PBM clients. Some state Medicaid programs have a long history of linking drug and other medical data through their management information system and of generating management and utilization review reports from that database. PBMs make greater use of data in provider reporting, but rarely have comprehensive databases linking drug and medical claims data.

Medicaid, which guarantees providers access to recipients, has less leverage than do PBMs in establishing pharmacy reimbursement. PBMs are not subject to formulary limitations imposed on Medicaid by OBRA '90. OBRA '90 requires each state to reimburse for all drugs that HCFA has negotiated rebate contracts. Private systems may be more responsive than government bureaucracy to adopting new programs or technology.

Current and Potential Role of PBMs for Medicaid and Other Government Agencies

Medicaid

PBMs provide services to Medicaid recipients to a very limited extent. No states have contracted directly with PBMs to manage the Medicaid prescription drug program. Several states have indirect contracts with PBMs through MCOs that have enrolled Medicaid recipients as part of states' managed care initiatives, but not all MCOs use a PBM to manage the drug benefit.

Some PBM services are potentially relevant for Medicaid programs. PBMs have sophisticated claims processing and data systems for handling administrative aspects of Medicaid drug programs. Their prospective and retrospective DUR and prior authorization programs parallel current state programs and possibly are based on the same criteria and algorithms. Formulary development and management programs also might be transferable to Medicaid programs. State Medicaid programs may wish to consider individually the component parts of a PBM service package, rather than approaching a PBM contract as "all or nothing." For example, mail order dispensing could have shortcomings for Medicaid populations, as may drug use management techniques involving financial incentives for patients.

Medicare

If a drug benefit is added to Medicare coverage, there could be a role for PBMs in filling the void at the federal level to provide and manage the drug benefit. The Medicare program could benefit from the efficient and flexible drug program designs offered by PBMs, including on-line P-DUR, physician profiling, and formulary management. Mail service programs offered by PBMs may be practical and accepted by Medicare beneficiaries, given the greater convenience they provide.

The impact of a PBM-managed Medicare drug benefit on pharmacists, pharmacies and the rest of the pharmaceutical industry would be much greater than the impact of a PBM-managed Medicaid drug benefit, since Medicare beneficiaries represent a major market.

Impact of PBMs on the Larger Pharmaceutical Market

The potential impacts of PBMs on the larger pharmaceutical market cannot be predicted with certainty. The impacts primarily will be seen in the pharmacy and pharmaceutical manufacturer industries, but conceivably there will be effects on wholesalers, patients and caregivers, prescribers, and clients.

Wholesalers indirectly are affected by factors influencing their customers (pharmacies) and suppliers (manufacturers). Patients and caregivers may be affected by changed access to restricted networks of pharmacies or availability of specific drugs if closed formularies are employed, but they also may realize improved quality and economy of drug prescribing and use. Physicians may experience time impositions related to PBM drug use management initiatives, but these impositions may be balanced by patient care enhancements derived from improved monitoring or clinical impact by PBM staff or agents. Continued information asymmetry is a distinct possibility between PBMs and their clients since it often is difficult to assess the savings and effectiveness of PBMs. Questions of how to gauge quality, economy, and outcomes are common, and purchasers do not know always where to look for answers.

Pharmacies

The effects of PBMs on pharmacies and pharmacists occur in financial, market, and care aspects of pharmacy operations and service provision. Reimbursement levels offered by PBMs, reflecting volume-discounted pricing, have an immediate effect on pharmacy revenues and profits. Decreased profitability will drive further consolidation, largely through horizontal integration, in the chain pharmacy sector, whereas independent pharmacies are more likely to exit the market. Pharmacies excluded from restricted panels have reduced revenue streams from dispensing fewer prescriptions and reduced scale of operations. Mail service dispensing removes prescription volume from community pharmacies, having the same impact on revenues and scale economies as do restricted panels.

If rebates continue and play a significant role in formulary decisions, then there will be continued emphasis on the pharmacist as 'formulary implementers.' Such a role, if not accompanied by professional and financial incentives, may preclude the pharmacist from performing a clinical function where his or her own judgment and experience operate in the patient's best interest. However, some analysts predict that rebates will become less prevalent, and that pharmacists and physicians will be capitated for drugs. Under these conditions, pharmacists may have professional and financial incentives to perform clinically-oriented drug management interventions. If drug capitation is isolated, and not linked with other services, this could impair pharmacists' and physicians' judgment and diminish patient access to needed drug therapies and other dimensions of quality. Similarly, if PBMs define cognitive services and disease management programs in clinical parameters, rather than merely by the potential for cost savings, providing such services could result in greater revenues and professional opportunities for pharmacists.

Manufacturers

For pharmaceutical manufacturers, the potential impacts of PBMs primarily will revolve around one area; rebates and market share changes associated with them. Rebates yield reduced prices and potential profits for manufacturers, since they are price concessions, but increased volume may result in enhanced revenue streams.

Throughout the study period we witnessed greater horizontal integration within the pharmaceutical industry, and several analysts predicted that this trend will continue. Such integration is designed to achieve production and marketing efficiencies; to ensure broad product lines and drug coverage; to maintain market power; and to serve as a countervailing force against the growth of PBMs. Integration is also occurring vertically. While further mergers between pharmaceutical manufacturers and PBMs do not appear likely, other kinds of alliances between industry and PBMs are emerging, such as joint ventures in disease management programs.

PBMs' aggressive pricing and rebate strategies can result in reduced profits margins and create market shifts that can put pressure on manufacturers' research and development budgets. Further, interviewees noted that PBMs have stimulated drug price competition that has resulted in less development of "me too" (therapeutically duplicative) products and a concomitant emphasis on "blockbuster" drugs (i.e., unique new therapies).

Conclusions

The world of PBMs is complex and dynamic, and PBMs have achieved success in several areas of drug program management. They employ a variety of techniques to manage drug use, some targeted towards patients, some towards pharmacists, and some towards prescribers. Although PBMs have grown, in terms of the covered lives they represent, data and/or evidence on the cost and quality of PBM activities are not always available, clear, or conclusive.

PBMs have some potential advantages and disadvantages for Medicaid and other government programs. They have extensive pharmacy provider networks and they have been successful in extracting favorable market reimbursement rates from pharmacists. However, they have been less successful than Medicaid programs in the area of rebates, due to lower rebate levels and percentages of products with rebates. PBMs' sophisticated claims processing and data management systems could have application for Medicaid or a drug benefit under Medicare. The uniqueness of Medicaid populations and the size of the Medicare population reflect potential challenges for PBMs. The lack of linkages between pharmacy and other medical data and newness of disease management programs may limit PBM abilities to assess and/or have meaningful impact on broader patient outcomes.

Implications of PBMs on the larger pharmaceutical marketplace fall primarily on pharmacies and pharmaceutical manufacturers since they are most directly affected by PBM policies and drug use management techniques. In both markets, PBMs affect revenue streams, with potential long range effects of industry consolidation and reduced access or quality.

The overall impact of PBMs on cost and quality requires more intensive and systematic study. Questions remain as to whether there are incremental enhancements in economy, efficiency, and quality associated with PBMs, and if so, at what cost? Several barriers to conducting future research on PBMs and answering these questions include:

- the proprietary nature of important data elements necessary for assessments;

- difficulty in defining meaningful baseline measurements against which cost savings, cost impacts, and quality can be measured;

- challenges in research design to control for numerous potentially causal factors in complex systems;

- difficulty in linking pharmacy claims data with data from other medical services.

To date, it appears the PBM industry has not given states a compelling reasons to establish direct contracts for managing their Medicaid drug programs. If or when more evidence becomes available about the influence PBMs have on cost and quality in drug programs, states will be better able to decide. The burden of proof lies with the PBM industry; the strength of their evidence will influence the path states will take.

I. Overview

Introduction

In 1995, the Health Care Financing Administration (HCFA) commissioned a comprehensive assessment of the pharmacy benefit management (PBM) industry and its impact on costs, quality of care, and the larger pharmaceutical market. HCFA's interest in PBMs was stimulated by the PBM industry's dramatic growth, both in terms of the number of firms and the number of people for whom PBMs provide services. Moreover, relatively little research on PBMs and their impact was available in the peer-reviewed literature; existing information generally was confined to the trade press and newspapers.

The following final report presents findings from a research study designed in response to HCFA's request for proposals. The study was conducted by researchers at the University of Wisconsin, Madison and the University of California, San Francisco between July 1995 and August 1996. By way of introduction, the authors review the available literature describing the history and growth of the PBM industry. This literature review also includes a description of existing information about PBMs' impact on costs, quality, and the larger pharmaceutical market. A section on research questions and study methodology follows. The next section, "Characterization of PBMs," serves a "primer" on PBMs and includes a typology of firms in the industry. The authors then review the existing literature on various functions performed by PBMs, such as formulary management and drug utilization review. The following section presents research findings based on interviews conducted with PBMs, their clients, and other stakeholders, such as pharmacists and benefits consultants. These findings describe the PBM industry and services provided by PBMs and include insights on cost savings achieved in a PBM environment. Next, the authors present the results of a survey of Medicaid pharmacy consultants and discuss implications for Medicaid (and other government) programs in light of the growth and development of the PBM industry. In particular, this section focuses on cost and quality issues under fee-for-service Medicaid programs compared to PBMs. The authors then provide an analysis of the impact of PBMs on other stakeholders in the pharmaceutical market. Finally, the report closes with ideas for future research on PBMs and recommendations to purchasers and other players (e.g., pharmacies, government agencies) in the pharmaceutical market.

Literature Review: An Introduction to PBMs

PBMs are organizations which apply managed care principles to prescription drug programs with a goal of optimal and cost-effecti e purchase and use of medications. PBMs are responsible for the design, implementation, and administration of pharmacy benefits programs. The four defining functions of PBMs are: (1) claims processing and adjudication, (2) pharmacy network management, (3) formulary development and management for clients, and (4) rebate negotiations with pharmaceutical manufacturers. In performing these functions, PBMs work in close association with health care payers and providers and drug manufacturers. (These inter-relationships are more fully discussed in Section III, "Characterization of PBMs: What Are PBMs and What Do They Do?")

There has been an evolution in the nature of PBM functions. Historically, many PBMs focused solely on prescription drug claims processing and adjudication services; as noted above, this function is still a defining attribute of PBMs. Later, PBMs adopted mechanisms to control drug costs, largely through negotiated discounts with pharmacy networks, formulary development and management, increased use of generic drugs, and rebates on brand drugs from manufacturers (Schulman, et al. 1996). Increasingly, PBMs are developing enhanced functions, including disease management initiatives, outcomes reporting capacities, and innovative interventions designed to improve quality of drug therapy, while decreasing overall health care expenditures. Indeed, Etheredge (1995) describes a continuum for the management of the pharmacy benefit, beginning with a first phase which emphasizes "improvements within a traditional insurance system," such as use of formularies, generic substitution, co-payments, and utilization controls. A second phase involves the application of purchasing power to secure discounts for pharmacy services and drug prices from manufacturers. A third phase introduces disease management technologies, including outcomes reporting and cost-effectiveness studies.

The numbers of PBMs in the United States have grown dramatically. According to a survey by SMG Marketing Group Inc., the number of PBMs grew 36 percent in 1995. A directory of PBMs published in May 1996 by *Managed Healthcare* lists 79 PBM firms, compared to 53 firms listed in the December 1994 issue.[1] However, estimates of the total number of PBMs vary widely for several reasons. The definition of PBM varies from a broad definition referring to firms which primarily perform claims processing and adjudication, to a more narrow definition which includes only "full-service" PBMs offering clinical management of the pharmacy benefit in addition to administrative services. Moreover, "PBM functions" are performed not only by PBMs, but also by health plans such as Kaiser Permanente, which manage the pharmacy benefit internally. Regardless of the total number of PBMs, it is undeniable that their market presence has grown tremendously in the last several years. Some estimates indicate that about half the U.S. population may receive pharmacy benefit services from PBMs (GAO 1995). Obtaining accurate information on the total number of PBM covered lives is difficult because one

[1] It is difficult to assess whether the directories account for most PBMs in existence, as the researchers did not have access to the primary data collected by these surveys, nor their response rates.

person may be covered by several PBMs providing different services. Double-counting inflates the total number of covered lives reported by PBMs.

Although PBMs have existed for a number of years, increasing health benefits program expenditures have rapidly increased purchasers' interest in PBMs as a mechanism to control cost inflation. Gibaldi (1995) conjectures:

> The PBMs rose to prominence by capitalizing on two trends: a doomed strategic plan embraced by the pharmaceutical industry [developing and marketing "me too" brand drugs], and an acceleration in America's private sector's efforts to curtail health care expenditures.

In 1980, expenditures for drugs and other medical nondurables (e.g., nonprescription drugs) amounted to $21.6 billion and represented about 8.5 percent of national health expenditures.[2] In 1990, this figure totaled $59.9 billion, and by 1994, it had risen to $78.6 billion, still representing about 8.5 percent of national health expenditures. Since 1990, the rate of growth in spending for prescription drugs has been slowing, as have the rate of increase in prescription drug prices, from an annual increase of 10 percent in 1990 to 3.4 percent in 1994 (Levit, Lazenby, Sivarajan 1996). According to Levit and colleagues:

> Price competition precipitated by an increase in generic drug availability, the rise of pharmaceutical benefit managers, and the emergence of alternative pharmacy sites forced consumer prices to fall.

More recent data indicate that in 1995, the price of prescription drugs rose 4.6 percent, reversing previous years' slowdown of the growth in prices. Drug companies refuted the data, claiming that a more accurate measure of drug price inflation indicates a 3.7 percent increase (Tanouye 1996).

The surge in the number and size of PBMs is also due to purchasers' increasing awareness that drug therapy often presents a less costly alternative to other medical care, such as doctor visits, hospitalization, emergency department use, etc. Payers have identified improved physician prescribing and appropriate patient drug utilization and compliance as methods to control costs (and hopefully improve quality), and they believe that PBMs will achieve these goals (Schulman, et al. 1996).

PBM clients are diversified -- about one-third are self-insured employers, another one-third are HMOs, and the remainder are PPOs, indemnity insurers, and Blue Cross and Blue Shield plans (Gemignani 1996). However, individual PBMs may specialize in serving a particular customer base; some have a large proportion of HMO clients and others mainly serve managed indemnity clients (e.g., self-insured employers, Blue plans).

---

[2] Spending on prescription drugs accounts for two thirds of spending in the nondurable products category.

Employers are increasingly interested in "carved-out" pharmacy benefit programs,[3] and reports in the trade press have bolstered beliefs that carve-out benefit plans, such as pharmacy and mental health, can reduce health care costs. A Foster Higgins survey (1995) indicates that 44 percent of employers w' h 500 or more employees provided a separate managed drug benefit in 1994. Over half of the 150 large employers surveyed by William M. Mercer, Inc. want to create a uniform managed drug plan for their employees enrolled in different health benefits options -- HMOs, point-of-service, and indemnity plans.[4] These employers may wish to carve out the drug benefit to a PBM which would serve all employees irrespective of their enrollment in different health benefit plans.

HMOs frequently contract with a PBM to manage their enrollees' drug benefit and provide the HMO with drug utilization data -- in 1995, about 57 percent of HMO enrollees in the United States were managed by a PBM (*CibaGeneva Pharmacy Benefit Report, 1996 Trends and Forecasts*). Medicaid agencies have not contracted directly with PBMs; however, managed care plans with Medicaid enrollees frequently subcontract management of the drug benefit to PBMs. The numbers of Medicaid enrollees are expected to increase as states move more and more recipients into managed care. Medicaid enrollees are higher utilizers of pharmaceuticals compared to an HMO average; the overall Medicaid population's PMPY average was about $260 in 1994, compared to an HMO average of $145 (*CibaGeneva Pharmacy Benefit Report, 1996 Trends and Forecasts*). It is important to note that these Medicaid figures include aged, blind, and disabled, and other high-drug-utilizing populations, whereas many new Medicaid managed care enrollees are AFDC recipients, a lower-utilization group.

History of PBM Industry

The history of PBMs is varied, likely because of diversity in PBMs' origins and functions. Taniguchi (1995) reports that existing PBMs evolved from different origins, ranging from pharmacy claims processors, mail order pharmacies, and HMOs. He underscores an important theme in the history of the PBM industry -- a connection between PBMs' evolution and their current functions and market niche. For example, a central PBM function is prescription drug claims processing. This function historically has been associated with third-party administrators and pharmacy services administrative

---

[3] Managed care organizations and other insurers may have agreements (similar to subcontracts) with firms or organizations that specialize in providing specific plan benefits (e.g., mental health services). The health services provided by such specialized firms are referred to as "carve-out" benefits. Pharmacy benefits are often covered in this manner due to some unique and specialized activities associated with processing prescription claims and providing pharmacy services as a benefit. Specifically, the high volume of drug claims and the large variety of drugs covered, with each prescription being a service encounter, has prompted the development of firms that specialize in processing and administering pharmaceutical services.

[4] Data from the 1995 National Survey on Advanced Pharmacy Benefits by William M. Mercer; as reported in *Managed Pharmaceutical Report* April 1996, p 10.

organizations (PSAOs); thus, evolution of PBMs from these origins is common.[5] Grabowski (forthcoming 1997) emphasizes the importance of the installment of on-line, electronic data interchange systems at retail pharmacies in the late 1980s. These computer systems transformed claims processing and adjudication by dramatically increasing the efficiency of the process and were a key factor enabling the growth of PBMs. In fact, two major PBMs, Merck-Medco Managed Care and PCS Health Systems, originated in the 1970s as PAID Prescriptions and Pharmaceutical Card Systems, Inc., respectively -- third-party prescription card programs that assisted public and private programs in administering their prescription programs, and later in controlling pharmacy benefit costs (Navarro 1995). In addition, Merck-Medco has roots in mail-service pharmacy (Medco Containment Services), and it remains a leader in this market.

Many other PBMs originated as internal pharmacy departments of managed care organizations and insurers that were developed into subsidiary companies to enter commercial markets. This group of PBMs includes, but is not limited to, Diversified Pharmaceutical Services (which grew out of United HealthCare), Pharmacy Gold and Paradigm (Blue Cross and Blue Shield of Minnesota and Maryland, respectively), WellPoint (Blue Cross of California), and Prescription Solutions (Pacificare Health Systems) (Navarro 1995). For-profit PBMs with origins in Blue Cross and Blue Shield organizations developed, in part, due to the Blues' prohibition against their plans conducting business outside their region or state. As for-profit entities or subsidiaries of for-profit holding companies, new PBMs avoided this legal dilemma.

Some PBMs originated from insurance companies or from pharmacy providers (groups of retail pharmacies or a specialized pharmacy, such as mail order). PBMs with pharmacy provider origins sometimes formed in order to provide in-house pharmacy services, claims processing, and database system management. RESTAT is a PBM which developed from a wholesaler-owned pharmacy computer system company. As data systems and analysis are a core competency for modern PBMs, RESTAT's origins may have provided a foundation that was fundamental for the firm's development into a PBM.

Growth of the PBM Industry

In 1993 and 1994, the pharmaceutical market was jolted by the purchase by major pharmaceutical manufacturers of the three largest PBMs. Merck and Co. purchased Medco Containment Services in 1993 for $6.6 billion (Freudenheim 1994; George 1994). SmithKline Beecham and Eli Lilly followed by purchasing Diversified Pharmaceuticals

---

[5] McEachern (1995) defines PSAO as "an organization either sponsored by a state pharmacy association or created by a group of independents, usually within a state or small region. . . Although many of the early PSAOs only contracted as a network for dispensing medications, today some can provide everything from claims administration and eligibility verification to drug utilization review, formularies, and disease management." McEachern notes that current PSAOs "are nearly indistinguishable from pharmacy benefit management companies."

(DPS) for $2.3 billion and PCS Health Systems for $4.0 billion, respectively (Woolsey 1994). The rapid growth of managed care worried pharmaceutical manufacturers who feared the loss of market share in an increasingly price-sensitive and competitive drug market. Manufacturers believed that vertical integration through ownership or alliance with a PBM would allow access both to distribution channels (to increase their drugs' market share) and information technology systems with clinical information on drug utilization patterns. Manufacturers would be poised for new roles as managers of health care with more direct access to the health care consumer, particularly as part of disease management programs (George 1994).

The long-term results of manufacturers' purchases of PBMs are not yet known, but preliminary information indicates mixed success. In July, 1996, Merck and Co. reported strong quarter earnings, adding that "results were bolstered by sales gains at its Merck-Medco Managed Care [PBM] business"(Naj 1996). Similar statements about positive results from Medco's acquisition have been issued since the merger (Tanouye 1995). Some financial analysts considered the PBM purchases critical to the future viability of drug manufacturers, particularly with regard to access to the market and the development of disease management programs (Fitzer-Schiller 1994). However, other analysts questioned the wisdom of the high-priced PBM purchases and doubted that the PBMs' future earning potential and market for their services warranted such intense interest from manufacturers (Sloan 1994). In July, 1996, an article in the Wall Street Journal reported that:

> PCS's weak performance and its mammoth price tag have become such a drain on Lilly's earnings that Wall Street is buzzing with talk that the drug giant may take a write-down on the acquisition (Browning and Burton 1996).

Analysts noted that PCS is implementing programs to shift market share to Lilly drugs, and given time, Lilly may benefit ultimately from its purchase.

Purchase of PBMs by manufacturers triggered a series of reactions by other stakeholder groups, and the PBM industry has witnessed further horizontal integration. Many non-aligned manufacturers sought alliances with the remaining independent PBMs; Pfizer Inc. forged agreements with Caremark and Value Health, as did Bristol-Myers Squibb with Caremark, to increase the presence of the manufacturers' products on the formulary. Large retail chain drug stores formed a PBM, Pharmacy Direct, to increase competition in the PBM market (George 1994; Freudenheim 1994). Consolidation within the PBM industry has taken place, as smaller firms have merged with each other or with larger PBMs, and even large PBMs have joined forces. For example, during summer 1996, ProVantage bought ScriptCard (CareStream) and Merck-Medco purchased Systemed. In 1995, large PBM Diagnostek was merged into Value Rx, a PBM subsidiary of Value Health, Inc.

Issues Relevant to the Growth of PBMs

Concern about the drug manufacturer-PBM mergers emanated from several directions. Critics complained that by allowing the mergers, the Federal Trade Commission (FTC) did not appropriately enforce federal anti-trust laws. In response to these concerns, Eli Lilly voluntarily signed a FTC consent agreement to establish a "fire wall" to prevent certain information from being exchanged between parent company and PBM; such information includes other manufacturers' confidential pricing bids to PCS. PCS also agreed to offer an open formulary (Freudenheim (b) 1994). Nevertheless, some concerns have remained. A survey of pharmacy directors in managed care plans reported that their greatest concern about the mergers was the potential for "inappropriate influence on formulary decisions" by the pharmaceutical industry (Lawrence, Weart 1995). The General Accounting Office (GAO) conducted a study to examine the impact of manufacturer-PBM mergers on formularies.[6] Some industry experts expressed concern that the cost-cutting efforts of a more consolidated and vertically-integrated pharmaceutical industry might result in diminished funds for research and development (Tanouye, Anders 1995). Etheredge (1995) echoes this concern, but also presents an alternative viewpoint:

> Given the economics of the pharmaceutical industry, it seems likely that the companies that depend on me-too drugs will find their profit margins and their ability to finance future research and innovation squeezed. Yet, the large, sophisticated PBM purchasers may also speed adoption of true breakthrough product development.

The debate about the mergers and alliances between PBMs and manufacturers has not been resolved. Some consumer groups have complained that the PBM-manufacturer mergers will hurt competition, increase consumer drug prices, and restrict the number of drugs available to patients (Rothschild 1994). With the rise of PBMs and "carved-out" benefits, patients must be ensured appropriate coordination of care by multiple organizations (health plans, PBMs, mental health providers) (Etheredge 1995). Those who defend the mergers note that no one pharmaceutical manufacturer has a leading product in all therapeutic categories, limiting manufacturers' presence even on formularies at PBMs they own. In addition, PBMs' ability to switch prescriptions to preferred products is determined by the willingness to cooperate by physicians, pharmacists, patients, and PBMs' P&T committees (Etheredge 1995).

Because the body of literature describing the cost-containment mechanisms PBMs employ, quality-of-care initiatives implemented, and the impact on the larger pharmaceutical marketplace is very limited, many unanswered questions remain. Schulman et al. (1996) describes PBM formularies, physician and pharmacist interventions implemented by PBMs, and their drug utilization review and disease management

---

[6] The GAO concluded that DPS did not alter significantly its formularies to favor SmithKline Beecham products before or after the merger. Medco added seven Merck products to the recommended formulary and dropped some competing, non-Merck products.

programs. He notes that the literature on results of PBM functions is "underdeveloped." Schulman and colleagues further comment:

> Pharmaceutical benefits managers offer the potential to improve pharmaceutical use in the United States by improving therapeutic practices and reducing pharmaceutical costs. However, these organizations cannot track the effect of their interventions on overall health outcomes. . . . Until comprehensive, integrated analyses are possible, these organizations will lack the ability to definitively show the effect of their programs.

Etheredge (1995) briefly discusses difficulties encountered in assessing true level of cost savings achieved by PBMs, effects on participants (e.g., patients, pharmacists, manufacturers) and potential applications of PBMs to government programs, such as Medicaid and Medicare. He calls for rigorous, empirical studies of the effects of PBM activities on patient outcomes, and the development of standards with which to assess PBM claims of improved outcomes and cost-effectiveness. The authors hope that the following final report will provide a foundation for these future research studies, as well as for those described in the conclusion of this report, on PBMs and the management of pharmacy benefit plans.

An Introduction to the Medicaid Drug Benefit

Like PBMs, state Medicaid programs administer a prescription drug benefit, although they may subcontract responsibility for some functions to an outside vendor. The following section serves as an introduction to the Medicaid drug benefit and includes information on reimbursement for drug costs, freedom of choice regulations, quality assurance, scope of service, and rebates.

Background Information

Drugs account for 7.4% of the $91 billion spent for services by Medicaid in 1992. Payment for drugs between 1975 and 1992 rose about eight fold, from $0.8 billion in 1975 to $6.8 billion in 1992. In 1992, Medicaid expenditures for drugs used by children and adults (who are primarily their parents) accounted for $1.6 billion, and drugs used by the aged and disabled accounted for the remaining $5.2 billion. Although the aged and elderly represent only 26 percent of Medicaid eligibles, these groups use almost 75 percent of the drugs reimbursed (*Health Care Financing Review* February 1995). Clearly, prescription drug benefit management is an important issue to the Medicaid program.

Federal regulations require States to submit a state plan describing the nature and scope of its Medicaid program. Under the current match program, the Federal government pays between 50 percent and 83 percent of Medicaid costs. In exchange,

some restrictions on State payments for Medicaid services are regulated by the Federal government. States are required to comply with the following principles:

- reimbursement must be adequate to assure participation of a sufficient number of providers so that recipients may have access to service at least to the extent available to the general public
- recipients are guaranteed freedom of choice to participating providers and managed care organizations
- services provided under the plan must be available throughout the State
- States must establish programs to monitor and intervene to assure quality care
- services provided must be sufficient in amount, duration and scope to reasonably achieve quality care

Although drugs are an optional service, all 50 State Medicaid programs reimburse for prescribed drugs. States are required to reimburse for family planning services (e.g., oral contraceptives) and drugs used by nursing home residents. States are free to impose restrictions on access to drugs including restricting formularies to prescription only drugs (i.e., no OTCs) and restricting access if "the excluded drug does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of such treatment" over other drug products. The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) mandates that state Medicaid programs implement specific drug utilization review (DUR) activities: prospective and retrospective DUR programs based on explicit criteria, effective January 1993; drug counseling of patients by community pharmacists; and educational programs designed to improve drug prescribing. The legislation also requires drug manufacturers to provide rebates to all Medicaid programs for their products to be eligible for Federal reimbursement. In exchange for the rebate agreement, states were required to eliminate restrictive formularies. Under OBRA '90 States could not restrict newly approved pharmaceutical products until six months after approval. This changed under OBRA '93, which repealed restrictions on formularies but required excluded drug products to be available through prior authorization.

Reimbursement

From the beginning, Medicaid reimbursement has been based upon the principle that providers' payments must reflect reasonable costs and reasonable charges. In 1976, the Health Care Financing Administration (HCFA) established the upper limit for drug reimbursement under Medicaid to the lower of:

1) a Maximum Allowable Cost (MAC) of the drug for certain multi-source drugs, (generic drugs) plus a reasonable dispensing fee; or

2) the Estimated Acquisition Cost (EAC) for the drug (the price generally and currently paid by providers for a drug in the package size most commonly purchased) plus a reasonable dispensing fee; or

3) the providers' usual and customary charge to the public for the drug.

Under current Federal regulations, States are free to establish their own payment limits provided the aggregate reimbursement is similar to payment under the specified upper limit standard (State Medicaid Manual, 1992). States generally apply the same approach outlined in 1976, adopt State MAC prices for multi-source drugs that are at or below the upper limits established by HCFA. The State Medicaid Manual advises States that AWP overstates the price that pharmacists actually pay for drugs by as much as 10-20 percent. Consequently, States have established EACs ranging from AWP less 4 percent to AWP less 13.5 percent (Pharmaceutical Benefits, 1995). The majority of States use AWP less 10 percent as the basis for EAC.

HCFA encourages States to perform periodic cost of dispensing studies to assure the dispensing fee reflects reasonable cost. Few states performed routine studies which may account for the Medicaid professional fees ranging from $2.50 to $5.77 (Pharmaceutical Benefits, 1995). Nineteen States have fees of less than $4.00 and 31 states having fees of $4.00 or more. A study by Adams, Gavin and Kreling of Medicaid reimbursement rates to pharmacies concluded that States are paying 95-100 percent of estimated total average costs, before profits, for prescriptions dispensed to Medicaid recipients (Adams, Gavin, Kreling 1995).

Freedom of Choice and Statewide Status

Medicaid regulations guarantee recipients the right to select any participating provider. While low participation rates of pharmacists could restrict recipients' freedom of choice, Adams, Gavin and Kreling (1993) report that participation rates are uniformly high across the States. However, pharmacies tend not to locate in areas of high poverty and concentration of Medicaid eligibles.

1915(b) Medicaid waivers provide States with the ability to waive recipient freedom of choice and state wide guarantee of service. Forty States have established Medicaid managed care programs under the 1915(b) waiver (Pharmaceutical Benefits, 1995). Recently states have moved to Section 1115 Medicaid waivers to implement statewide MCO programs. While recipients are guaranteed freedom of choice of MCO, MCOs may restrict recipients access to pharmacies in the MCO networks.

Quality Assurance

Several States have had drug utilization review (DUR) programs since the mid-1970s. In 1990, Congress required all State Medicaid programs to establish DUR programs. Effective January 1 , 1993 States are required to implement DUR programs that consists of prospective DUR, retrospective DUR, and an educational program (Code Federal Regulations, 1996- 42 CFR 456). States were encouraged to establish on-line, real-time prospective DUR with the Federal government paying 90 percent of the cost of development. Federal regulations require pharmacists to make reasonable attempts to gather information on patients including age, sex, medical conditions and drug histories and offer to counsel patients on their drug use. A GAO report (U.S. General Accounting Office, 1996-GAO/AIMD-96-72) on the status of online Pro-DUR effective April 1, 1996 identified 29 States with operational Pro-DUR programs and 16 States with plans to implement P-DUR programs by 1997. Six States have no plans to implement P-DUR, two States, Tennessee and Arizona, have their beneficiaries enrolled in managed care programs. States also are required to establish retrospective DUR programs to educate physicians and pharmacists to identify and reduce the frequency of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

Rebates

Rapid increases in drug prices in the 1980's, combined with Medicaid program's adoption of restrictive formularies in response to increase in Medicaid drug expenditures, led Congress to enact major changes to the Medicaid drug program (Pollard, Coster 1991). The legislation, incorporated into OBRA '90, required pharmaceutical manufacturers to agree to provide rebates to all Medicaid programs for their products to be eligible for Federal reimbursement. It provided State Medicaid programs with discounts commonly provided to other purchasers (e.g., hospitals, HMOs), most with fewer covered lives. In exchange for the rebate agreement, States were required to eliminate restrictive formularies. States could continue to restrict access to drugs through a prior authorization process. States may reimburse for sole source products or innovator multi-source products without a manufacturer rebate agreement if: 1) the State determines it is an essential drug; 2) it is rated 1-A by the FDA; and 3) prior authorization is obtained for these exceptions (Public Law 101-508). Revisions to the law in 1992 (Public Law 102-585) required manufacturers to pay quarterly rebates to States equal to the greater of 15.1 percent of Average Manufacturer Price (the price paid by drug wholesalers) or AMP

minus the best price beginning in 1996. The rebate for non-innovator multi-source drugs is 11 percent.

In 1995, HCFA reported that rebate payments resulted in a 4.6 percent reduction in drug expenditures in FY 1991, a 13 percent reduction in drug expenditures in FY 1992 and a 17 percent reduction in drug expenditures in FY 1993 (*Impact of the Medicaid Drug Rebate Program*, 1995).

II. Research Questions and Methods

Despite the dramatic growth of PBMs described in the Introduction, there have been no systematic, empirical studies of the organization, scope of services, types of clients and impact of PBMs on cost, quality, and the larger pharmaceutical marketplace. The current project was designed to generate information in each of these areas which could then be tested in large-scale, quantitative studies. Our research was designed to be a fast-track monitoring study to provide timely information to HCFA and state Medicaid programs.

Research questions

The research project focused on four main issues:

1. Characterization of PBMs. A major research objective was to provide organizational data characterizing PBMs through the conduct of a literature review and the development of a typology of PBM characteristics.

2. A comparison of costs and quality of care (including improvements in drug therapy and patient outcomes) in the provision of pharmacy benefits, given three different situations: (1) when benefits are provided to Medicaid recipients under fee-for-service arrangements; (2) when benefits are provided to Medicaid recipients under managed care contracts with PBMs; and (3) when benefits are provided by PBMs to privately insured enrollees.

3. An analysis of the potential impacts of PBMs on Medicaid programs, a survey of Medicaid pharmacy consultants about interest in direct contracting with PBMs, issues raised by PBMs for consideration by Medicaid agencies, and the potential role of PBMs for Medicaid, Medicare, and other government programs.

4. An analysis of the potential effects of PBMs on the larger pharmaceutical marketplace including, but not limited to, pharmacies and pharmacists, pharmaceutical manufacturers, health benefits consultants, wholesalers, physicians and patients.

Overview of Research Design and Data Sources

To characterize PBMs and study their impact, the researchers used a case study methodology. Data were collected from several sources: site visits at PBMs; in-depth interviews with other stakeholders (i.e., PBM clients, consultants at state Medicaid programs, health benefit consultants, and representatives from the retail pharmacy and pharmaceutical manufacturing industries); and perusal of the print media and other data sources. Extensive notes were taken during each interview, and in some cases, additional information was incorporated based on taped recordings. Interviews with all respondents (exclusive of site visits to PBMs) averaged about one hour.

Sampling Approach

PBMs. A key goal of the study was to characterize PBMs and their impact by examining PBMs of various sizes, ownership status, and geographic locations. Accordingly, the PBMs were chosen to represent a range in the number of covered lives, ownership status, and geographic regions of the country. Variation along other dimensions, such as PBM origin and number of Medicaid enrollees, was achieved without using these characteristics as selection criteria. While the PBMs were not chosen randomly, they represent the overwhelming proportion of PBM covered lives.

Eight PBMs were approached to enroll in the study by the research team, but due to logistical difficulties, a case study of one PBM could not be conducted. Hence, a total of seven PBMs were studied intensively.

Headquarters of the seven PBMs are distributed across seven states, and most regions of the country are represented. Large and small PBMs are represented in the sample in order to gauge differences in PBM capabilities that might be associated with size and scale. For example, large PBMs may realize greater economies of scale and may have the resources to establish an internal clinical division and their own pharmacy staff that would enable the PBM to perform more clinical functions. The sample was chosen to reflect the variety of ownership relations characterizing the PBM market, namely, ownership by pharmaceutical manufacturers, insurers, and pharmacies.

Medicaid Program Pharmacy Consultants. To obtain a sample of pharmacy consultants, states were selected that were believed to have had experience with, or interest in, direct contracting with a PBM, as well as states having a large number of Medicaid recipients enrolled in managed care organizations.

PBM Clients. Given the case study methodology employed in this research, sampling of PBM clients (e.g., managed care organizations, insurers, and employers) was purposive. Four MCO/insurers were chosen because they were clients of PBMs under study; one was selected because it had recently changed PBMs and it was considered important to understand the dynamics of change; and another was selected because it has a Medicaid managed care contract with the state. Employer groups were chosen according to the following criteria: they were clients of PBMs under study or they were employer coalitions involved in major new initiatives in contracting with PBMs.

Informed consent procedures

The research team obtained informed consent for study participation from all interviewees. After an introductory telephone call describing the purpose of the study, a standard letter was mailed or faxed to potential interviewees which described the research policies to protect participants' confidentiality. In a follow-up telephone call, the researchers reviewed the contents of the letter and confirmed participation in the study via an in-person or telephone interview. These informed consent procedures were approved

by the committees on human research at the University of Wisconsin (Madison) and the University of California at San Francisco.

Study Timetable

The study was conducted over a fourteen-month period (July, 1995 through August, 1996). Survey protocols were developed by the research team and reviewed by an expert panel.[7] A pre-test of the PBM survey protocol was conducted in November, 1995, with a president and chief executive officer of a small PBM (results are not included in the study). Site visits to PBMs and other interviews were conducted between January and May of 1996. Priority was placed on a systematic and objective approach, including use of a uniform interview protocol for each category of respondent. Summaries of the data were presented to the expert panel in May, 1996, at an all-day meeting in San Francisco for review and comment. Their suggestions for greater clarification and additional information prompted additional interviews and follow-up telephone calls with PBM staff and members of other stakeholder groups. A seminar presenting the study's findings and implications was presented to HCFA and other governmental officials in August, 1996.[8]

In August, a copy of the draft report was sent to the expert panel members for review. Copies of the draft final report also were sent to each PBM for its review of the accuracy and completeness of statements made regarding their PBM and any other relevant data. PBMs were permitted to comment on the interpretations of the data made by the research team, but the researchers made it clear that they were not bound to incorporate these changes.

Methods

Literature Review. A comprehensive literature review was undertaken to examine what the peer-reviewed literature and trade press reports revealed about the operations of PBMs and their effects on quality, cost, access, and the larger pharmaceutical market. This review helped to develop a typology of PBM characteristics that incorporated variables such as history, origin, organization, growth, scope of services, types of clients, and numbers of covered lives. The literature review also included articles on the administrative and drug-use control functions performed by PBMs (e.g., mail order services, drug utilization review efforts, etc.). Although this literature does not focus on activities in PBM settings, it was felt that knowledge of the impact of these functions in other settings would illuminate understanding of their applicability in PBMs. Computer data bases used for the literature review included Nexis, Medline, and ABI/Inform.

---

[7] The expert panel included: Deborah A. Freund, Ph.D.; Mary Anne Koda-Kimble, Pharm.D.; Harold S. Luft, Ph.D.; Stephen W. Schondelmeyer, Pharm.D.; David G. Schulke; and Patricia Wilson.

[8] The following governmental agencies were represented at the HCFA seminar: HCFA (Bureau of Policy Development, Office of Research and Demonstrations, Health Standards and Quality Bureau, Medicaid Bureau), the Office of the Inspector General, the Food and Drug Administration, and the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

Site visits at PBMs. Site visits were designed to provide a better understanding of PBMs -- their history, functions, and impact -- through interviews with executives and other staff. Interviews were conducted at seven PBMs by a team of two-to-four members of the research team. Time spent at PBMs ranged from six hours to two days, depending upon the time allotted by PBM personnel. After all site visits, researchers made follow-up telephone calls to gather additional data and to clarify interview information that was unclear. The research team met with directors and vice presidents in the departments of marketing, pharmacy services or pharmacy network, clinical development, business development, pricing, and general counsel, as well as presidents and chief executive officers. Depending on the preferences of the PBM, the number of individual and group interviews at each site ranged from one to fourteen. In most instances, summaries of interview notes were sent to the PBMs to solicit their feedback on the accuracy and completeness of factual information.

Interview respondents were asked about company background, clinical services and programs, pharmacy network, cost savings, quality of care, pharmacy fee structures, charges to clients, rebate levels and arrangements, and future strategies. Given the sensitive nature of the information sought, the researchers exercised great care to guarantee anonymity to individuals and organizations. For this reason, no PBM names are used in this report.

Interviews with other stakeholders. To validate and triangulate information obtained from interviews with PBM representatives, extensive interviews were conducted with a total of ten PBM clients (employers, employer coalitions, managed care organizations and insurers). These interviews focused on PBM clients' perspectives on the dynamics, viability, usefulness, and impact of PBMs on costs, quality and outcomes. Interviewees were asked about their reasons for choosing a PBM to manage the drug benefit, why they changed PBMs (if applicable), the kinds of services provided by the PBM, quality-of-care reporting requirements, payment mechanisms for PBM services (e.g., fee-for-service, capitation, other risk-sharing arrangements such as savings guarantees), perceptions of whether the PBM saved money and improved quality, and whether and how PBMs' performance differs from drug benefits provided under the Medicaid program.

Pharmacy consultants at six state Medicaid programs were interviewed to identify the extent to which their state had contracts with PBMs to manage the drug benefit ("direct contracting"). Respondents also were queried about potential advantages and disadvantages of using PBMs to manage the state's drug benefit program. Another avenue of inquiry was the extent, advantages and disadvantages of "indirect" contracting, that is, enrollment of Medicaid recipients into managed care organizations subcontracting with a PBM to manage the drug benefit.

Supplemental data sources. Interviews were supplemented by review of annual reports, local newspaper and journal articles on PBMs and related issues, and other

publicly available data (e.g., public hearing transcripts, government documents analyzing PBMs, and reports by private consultants). Examination of these data sources provided additional information and insights regarding PBMs' organizational structure, current initiatives, market share, and impact on other market stakeholders, as well as perceptions from clients about PBMs' performance.

Data Analysis

To ensure objectivity and comparability across PBMs, data collection was systematized by using a standard interview protocol and selecting similar respondents for interviews across all sites. As noted earlier, interview protocols were arranged by topic area (see Appendix A). We analyzed the data across the seven PBMs by each topic area addressed in the protocol (e.g., descriptions/results of PBM services, cost-cutting initiatives, quality improvement mechanisms, cost savings estimates, etc.). The purposes of the cross-PBM analyses were to document the commonalties and the range of variation in the characteristics of the PBMs, the clinical and administrative functions they perform, the dynamics of change they experience, their similarities and differences from the Medicaid program, and the assessments of respondents concerning the effects of PBMs on cost savings and quality improvement. These same topic areas were analyzed across the ten PBM clients; their perceptions and assessments of PBMs were incorporated into the PBM analyses. As noted earlier, summaries of the data were presented to the expert panel in May, 1996. Panelists' insights were incorporated into the analyses presented in the final report.

III. Characterization of PBMs

A characterization of the universe of PBMs is one of the primary objectives of this study. The following section serves as a "primer" on PBMs, describing the functions PBMs perform and the relationships they establish with other types of organizations in order to successfully achieve their goals. A typology of PBMs follows.

What are PBMs?

As their name implies, PBMs exist to administer and manage prescription drug programs. They function in this capacity for a variety of clients, including large and small employers, insurers, managed care organizations, government agencies, labor organizations, and others for whom the task of administering their own prescription drug program is not feasible economically or functionally. Beyond the direct connection between PBM and client, the "world of PBMs" is characterized by complex relationships among a variety of stakeholders. Some have referred to these groups as the "five Ps": purchasers (e.g., employers), payers (e.g., insurers, managed care organizations), providers (pharmacists and physicians), patients, and policy makers. The complexities of these inter-relationships are illustrated by the flow of economic resources (*figure 1)*, as well as the flow of information and services (*figure 2)*. Examination of how economic and informational resources flow among PBMs and the various groups with which they interact helps characterize how PBMs work and the functions that they perform.

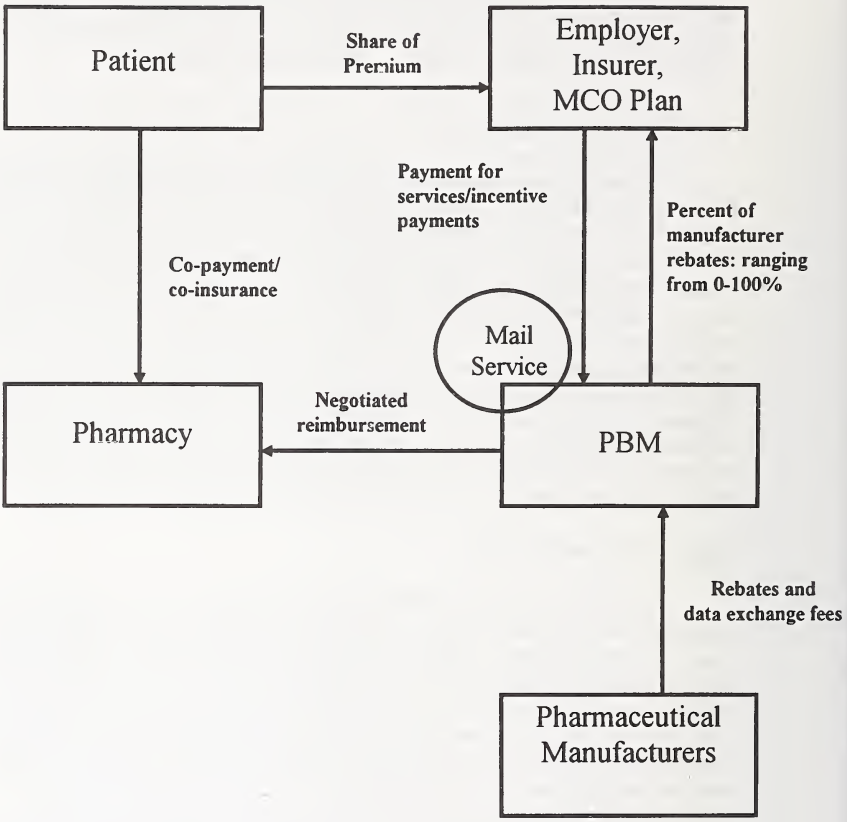
Figure 1: The flow of money

The PBM client, such as a health plan, pays the net prescription cost (pharmacy fee less patient cost share amount) and a per claim or transaction fee to the PBM for claims processing and adjudication; PBMs are accepting capitated payment arrangements for these combined amounts, but this is still a relatively rare phenomenon (see section on charges to clients.) Some PBM clients may pay additional amounts for "add-on" services, such as special drug utilization reports or disease management programs. Money flows from the PBM back to the client in the form of rebates the PBM collects from drug manufacturers and shares, to varying degrees, with clients.[9] An additional source of revenues for PBMs comes from manufacturers' payments for PBM drug use and expenditure data. PBMs reimburse network pharmacies for drug costs at a negotiated discounted rate. Pharmacies also collect co-payments or co-insurance from patients' for their prescriptions. When PBMs have in-house mail service pharmacies, they assume the role of pharmacy provider or co-insurer and retain the reimbursement amounts and co-payment for dispensing the prescription.

---

[9]Clients can then choose to share these rebate dollars with their medical groups or IPAs, but this is rare. See "Colorado HMO Tries Incentives to Influence Prescribing Patterns," by Mary-Ellen Deily in *Managed Pharmaceutical Report* July 1996:3.

The World of PBMs
Money Flow



Adapted from General Accounting Office: Pharmacy Benefit Managers: *Early Results on Ventures with Drug Manufacturers*. GAO/HEHS-96-45, Washington, DC, 1995, page 6.

Figure 1

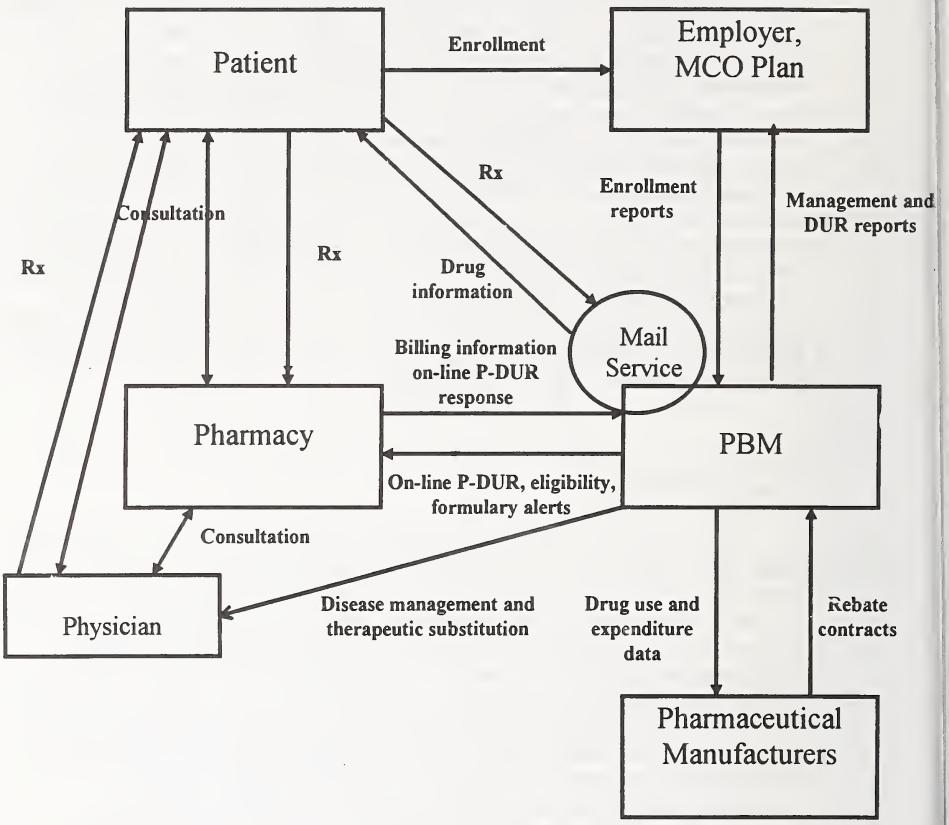
Figure 2: The flow of information and service

The PBM receives enrollment reports from its clients in order to properly adjudicate prescription claims and manage clinical drug programs. Clients receive regular reports on drug utilization and expenditures from the PBM. Claims data flow electronically from the pharmacy to the PBM, and P-DUR alerts are transmitted electronically to the pharmacy's computer terminals. The PBM sells data (stripped of patient identifiers) on utilization patterns and expenditures to drug manufacturers and other organizations (e.g., IMS). PBM pharmacists contact physicians directly about specific prescribing decisions. Most PBMs profile physicians' prescribing patterns and send these results directly to physicians or to the health plan of which the physician is a member. Information about the care of targeted chronic conditions is also communicated to physicians, as are practice guidelines, typically in the context of disease management programs. Pharmacists contact physicians about changes in drug therapies including, but not limited to, changes in drug dosage and duration. In both retail and mail service sectors, pharmacists interact with patients in person or by telephone, and may also provide patients with written information about drugs or chronic medical conditions, especially in the context of disease management programs.

What do PBMs do?

Since each PBM client may have different needs associated with its drug program, PBMs offer a wide array of services and arrangements to fulfill them. One way to consider what PBMs do is to categorize their activities into two main groups: administrative functions and drug use control activities. A list of PBM administrative and drug use control activities is shown in Table III.1. Administrative functions include activities associated with the mechanics of providing prescription services to beneficiaries such as maintaining a network of retail pharmacy providers and a mail service pharmacy option, and providing claims processing, benefit design, and record keeping and program reporting. Drug use control functions involve "managing" drug use to reduce costs and maintain or improve quality. These functions include policies and programs to affect drug use targeted towards pharmacists, patients, and prescribers, such as formulary development and management, drug utilization review (DUR), disease management programs, and patient compliance programs. These drug use control activities sometimes are referred to as "clinical programs" by PBMs.

The World of PBMs
Flow of Information and Services



Adapted from General Accounting Office: Pharmacy Benefit Managers: *Early Results on Ventures with Drug Manufacturers*. GAO/HEHS-96-45, Washington, DC, 1995, page 6.

Figure 2

Such a dichotomy can be useful to organize what PBMs do, but the categorization is somewhat arbitrary and some functions may overlap categories. For example, benefit design is categorized as an administrative function, yet the type and level of cost sharing required by patients (co-payments, co-insurance, or deductibles) can have considerable effects on drug use particularly if differential cost sharing provisions are present to encourage use of specific drug products. Similarly, negotiating and managing rebates are administrative activities, but they are associated with drug use behavior and how behavior is modified or influenced through drug use control activities.

The dichotomy also is useful if one considers drug program cost to be a multiplicative function of utilization and cost (total cost = utilization * cost per unit). Drug use control functions affect the utilization variable, and administrative functions are associated with cost variables. The overall goal of a PBM is to achieve cost savings for the client while maintaining quality. "Managing" drug use is a central focus of PBM activity; the mechanisms a PBM uses to achieve this goal differentiates it from competitors. While "cost containment" is a priority for many clients, focusing solely on the cost component of the drug plan equation may not achieve optimum results for the total costs of health care.

In the sections of this report that follow, we present information on PBM functions and their impact on costs and quality, based on published articles in the trade press and peer reviewed literature, as well as data collected from interviews with PBMs and their clients.

Typology of PBMs

The typology is derived from directories and lists of PBM addresses accumulated via a literature search and contacts knowledgeable about the industry. Three primary sources of information we used were directories in the May 1995 and 1996 issues of *Managed HealthCare*, a directory in the 3 April 1995 issue of *Business Insurance*, and lists of addresses obtained from the American Pharmaceutical Association (APhA). These sources of addresses and additional information from the directories are denoted by "source code" labels, i.e., MHC, BI, and APhA, respectively (see Appendix B).

We identified a total of 107 PBMs and have compiled an aggregate listing by combining data from all sources (see Appendix B). The aggregate list includes addresses and phone numbers and other categorizing data elements that were available. Categorizing data elements include covered lives, prescriptions per year, year they began providing PBM services, and number of pharmacies under contract. For 18 of the PBMs, the address was all the information we had available. For the other 89 PBMs we have

Table III.1: Categorization of PBM Activities

Administrative Functions

Establish and maintain network of providers
- recruit pharmacies
- negotiate prices and payment terms and contract with pharmacies
- monitor/audit performance

Claims processing
- online adjudication
- record keeping and reports to clients
- payment to providers and fiscal intermediary duties

Benefit design
- covered drugs, exclusions, limits
- cost-sharing provisions (differential co-payments for generic or preferred drugs)
- mail order dispensing

Information Management
- risk assessment
- profiling

Pharmacoeconomic studies

Drug Use Control Functions

Formulary and formulary related activities
- P&T committee
- provider incentives (RPh)
- patient incentives
- rebate management
- prior authorization
- therapeutic interchange

Drug Use Review
- retrospective-DUR
- prospective-DUR (some PBMs use the term "concurrent-DUR")
- DUR interventions
  - "academic detailing"
  - provider education (MD RPh)

Disease Management
- therapeutic outcomes management

Patient Compliance
- patient education, e.g., newsletters
- phone reminders

done some categorizing to describe the character of the industry. Those categorizations are described below. Since not all firms reported all data, the totals for tables vary, as do the corresponding computed percents.

It is important to note that the PBM industry is dynamic, and our typology is only as good as the information sources it is based on. New market entrants, exits, mergers, and name changes make PBMs a "moving target" as an industry to describe and characterize. Although we have attempted to provide a current and accurate description in this typology, it likely will be out-of-date and contain errors by the time our final report is submitted. Readers are cautioned about this limitation. Nevertheless, we provide the following summaries and comments to help describe the PBM market.

Location

Geographically, PBMs are dispersed throughout the nation as shown in Table III.2 (based upon headquarters locations listed in the directories). California has the most PBMs which could be related to MCO activity there, total state population, or a concentration of technologic expertise within the state. Conceivably, logistics could play a role for a PBM trying to provide services to clients, but geographic distance is not an overly restrictive impediment given the technology based nature of core PBM functions (claims processing, formulary activities, pharmacy panel contracting, etc.).

The number of covered lives reported by PBMs in each state is included in the table. There is some relationship between the number of PBM headquarters in the state and number of covered lives, but the data are skewed by the largest PBMs.

Service Area

Most of the PBMs report their service area as "national" and several include US territories and/or Canada or Mexico within their service area. For many PBMs this likely reflects their service area capabilities rather than their actual client distribution. It might not be logistically realistic for this high proportion of PBMs to provide service nationally, especially the smaller PBMs.

Table III.2
PBM Headquarters Location

Headquarters Location	Number (Percent)	Covered Lives (millions) [a,b]	Covered Lives (Percent)
California	9 (12.3%)	29.2	8.1%
Texas	7 (7.8%)	20.5	5.7%
Illinois	6 (6.7%)	19.8	5.5%
Pennsylvania	6 (6.7%)	14.8	4.1%
Florida	5 (5.6%)	1.2	0.3%
Minnesota	5 (5.6%)	68.6	19.0%
Missouri	5 (5.6%)	44.0	12.2%
Ohio	5 (5.6%)	8.5	2.4%
New Jersey	4 (4.5%)	58.8	16.3%
New York	4 (4.5%)	2.2	0.6%
Wisconsin	4 (4.5%)	7.7	2.1%
Connecticut	3 (3.4%)	7.2	2.0%
Georgia	3 (3.4%)	1.5	0.4%
Arizona	2 (2.2%)	57.3	15.8%
Arkansas	2 (2.2%)	1.8	0.5%
Kansas	2 (2.2%)	0.5	0.1%
Maryland	2 (2.2%)	0.1	0.1%
Michigan	2 (2.2%)	0.4	0.1%
Nebraska	2 (2.2%)	1.3	0.3%
Oregon	2 (2.2%)	NR	NR
Utah	2 (2.2%)	1.7	0.4%
Virginia	2 (2.2%)	10.5	2.9%
All Others	5 (5.6%)	NR	NR
Total	89 (100%)	360.8	

[a] Total of 72 PBMs reported covered lives in either the MHC (1996) or BI (1995) directories

[b] Reported covered lives exceeds the national population because several PBMs may provide services for the same individuals (e.g., separate PBMs provide formulary and mail order) or the same PBM may report on the same covered lives more than once (e.g., once each for mail order and claims process)

The majority of PBMs report their origin as being a managed care organization or PBM (Table III.3). Other "origins" include groups of retail pharmacies, third-party administrators, insurance companies, and prescription mail order firms. A common theme in the origin of PBMs is a connection to the function of claims processing, either as an organization that provided processing services, submitted claims, or reviewed claims for analysis and evaluation.

Table III.3
PBM Origin

Origin	Number [a] (Percent)
Managed Care Organization	23 (29%)
Retail Pharmacy	17 (22%)
Pharmacy Benefit Manager	15 (19%)
Other [b]	9 (12%)
Third Party Administrator	6 (9%)
Indemnity Insurance	5 (6%)
Mail Order Pharmacy	3 (4%)
Total	78 (100%)

[a] Percents based on 78 firms reporting origin in either 1995 or 1996 MHC

[b] Other = Alternative site health care, distributor/wholesaler, pharmaceutical services consultant, industry association, home care

Size

Categorizing the PBMs by the number of covered lives reveals their relative sizes and reflects the concentration of the industry. Covered lives were available in both the *Managed HealthCare (MHC)* and *Business Insurance (BI)* sources, thus both are included in the aggregate listing. We chose the *MHC* figure as our primary size figure, since there were more PBMs in the *MHC* listing. Most of the covered lives numbers were consistent across the sources, but there are some exceptions (see Table III.4).

Size also can be denoted by the number of prescriptions dispensed; there tends to be a correlation between these measures. As might be expected, the year of origination for providing PBM services also tends to be related to size; the larger PBMs often have been in existence longer. A table summarizing these size categorizations is provided (Table III.4). The table includes the number of covered lives from both sources, number of prescriptions, size of pharmacy panel (number of contracted pharmacies), and year of origination. Conceivably, a PBM's size also should correlate to their service area; the larger PBMs likely have a more national client base. Unfortunately, since most PBMs reported a national service area that they potentially could service rather than the market they actually service, this probable correlation cannot be substantiated.

Table III.4
PBM Covered Lives, Rxs, Network, Year of Origin, Headquarters State

Name	Covered Lives MHC 1996	Covered Lives BI 1995	Rx per Year 1996	Pharmacies under Contract 1996	PBM Services Since*	State Hdqtr
PCS Health Systems Inc.	56000000	56000000	320000000	54000	1969	AZ
Merck-Medco Managed Care	47000000	41000000	180000000	52000	1965	NJ
Argus Health Systems, Inc.	30000000	0	150000000			MO
ValueRx	27000000	16000000	56000000	42000	1985	MN
Diversified Pharmaceutical Services Inc.	26000000	14000000	100000000	43000	1976	MN
Caremark Prescription Service	15000000	14000000		53750	1985	IL
Pharmacy Gold Inc.	15000000	18000000	83000000	35000	1986	MN
TDI Managed Care Services Inc.	11000000	11500000	30000000	40000	1982	PA
Integrated Pharmaceutical Services	10500000		18000000			CA
Alta-Rx First Health	10000000		80000000			TX
First Health Services Corp.	10000000		76331000			VA
Wellpoint Pharmacy Management	10000000		58000000			CA
Advance Paradigm Inc.	9000000		50000000			TX
Express Scripts Inc.	8600000		30000000	37000	1986	MO
National Prescription Administrators Inc. (NPA)	6750000	6500000		51000	1978	NJ
Managed Prescription Services (MPS)	5000000	3500000	30000000	33000	1984	MO
Prudential Pharmacy Management	5000000		19000000			NJ
Restat	5000000	5000000	28000000	45000	1985	WI
Aetna Pharmacy Management	4800000	4663417	14000000	3800	1985	CT
Prescription Solutions	4000000	3200000	3200000	30000	1989	CA
RXConnections	4000000		73000000			OH
MedImpact Pharmaceutical Management Inc.	3800000		27000000			CA
General Computer Corp.	3500000	3703828	20000000	40000	1989	OH
ProVantagePrescription Management	2400000		14000000			Wi
Mednet/Medi-Claim	2000000		3000000			PA
Consultec Inc.	2000000		20000000			GA
WHP Health Initiatives, Inc.	1800000					IL
RxAmerica	1600000	800000	7000000	33000	1994	UT
Eagle Managed Care	1500000		6000000			PA
Home Pharmacy	1500000	2000000	650000	37000	1983	IL
United Managed Care Inc.	1300000					AZ
Curaflex Prescription Services Div Coram	1200000					NE
General Prescription Programs Inc.	1200000		3866000			NY
PharmaCare Management Services	1200000		7800000			RI
RxPrime	1200000					CT
Pequot Pharmaceutical Network	1100000	750000		15000	1992	CT
Allscrips Pharmaceuticals Inc.	1000000		7000000	200	1986	IL
Inteq Group Inc.	1000000	400000	3000000	28937	1992	TX
Pharmacy Service Corp of New York	1000000		6000000			NY
Wal-Mart Stores Inc.	1000000					AR
Integrated Health Concepts	800000		500000			CA
PAI	800000		3000000			AR

* Information about dates of PBM origin was obtained from *Business Insurance*, Directory of Pharmacy Benefit Management Companies, April 1995

Name	Covered Lives MHC 199	Covered Lives BI 1995	Rx per Year	Pharmacies under Contract	PBM Services Since	Sta Hdqtr
Universal RX	535000		2910000			VA
FFI Rx Managed Care	500000		1000000			FL
FFI Rx Managed Care Inc.	500000	600000	3000000	22000	1993	OH
Medi-Mail	500000		1200000			NV
Medi-Mail	500000					IL
Continental Managed Pharmacy Services Inc.	500000		400000			OH
Pharma-Link Inc.	500000		2000000			KS
Certifax Pharmacy Services	450000	450000			1989	OR
Managed Pharmacy Benefits Inc.	400000		30000000			MO
Pharmacy Services Group	400000		2500000			FL
Claimspro Health Claims Services Inc.	350000	350000		37000	1987	MI
Primextra Inc.	350000		1500000			MN
Diversified Prescription Delivery Systems	300000		1000000	32000	1963	PA
Eckerd Health Services	300000		1700000	34000	1995	FL
InfoCare Rx	300000	1500000		20000	1986	TX
PBM- Plus	300000		2000000			WI
Pharmacy Network National Corp.	250000		1200000			NC
ARAZ Group	245000					MN
United Provider Services	215000		1400000			TX
Pharmacist Service Group Inc.	175000		1100000			OR
BeneScript Services Inc.	150000		750000			G
Choice Drug Systems Inc.	114325	250000	1524440		1984	M
National Pharmaceutical Services	110000	110000		20000	1990	NE
OPN Open Pharmacy Network	50000		0			UT
Abbey Pharmacy Network	25000		100000			CA
Prescription Network of Kansas	23000		152000			KS
Managed Care Rx	11000		480000			PA
Cystic Fibrosis Services Inc.	7000		80000			MD
Medical Matrix						TX
National Medical Health care System Inc.						NY
OPTIUM Pharmacy Services						NY
AmeriKind Pharmacy Network Kmart Corp.			55000000			MI
APB America				18000	1994	WY
Benecard Services Inc.						NJ
Independent Pharmaceutical Consultants Inc.		900000			1991	MO
Kroger Managed Prescription Drug PRogram		150000		38000	1992	OH
Longs Drug Stores						CA
Managed Prescription Network				32000	1988	PA
MaxorPLus						TX
Medicap Pharmacy Inc.						IA
National Data Corp.						GA
Pharmacon Consultants						CA
Pharmacy Select Inc.						WI
Prescription Management Services						IL
Prescription Management Services Inc.			350000			F
Priority Pharmacy						C.
ProxyMed Inc.						FL

Market concentration can be an important descriptor of an industry. Table III.5 shows the number of PBMs categorized by the number of covered lives they reported. The table also includes 4-firm, 8-firm, and 20-firm concentration ratios based on the percent of total covered lives represented by the top 4, 8, and 20 firms respectively.

A caution with the size variable is warranted. Many PBMs provide both mail service prescriptions and claims processing/benefit management for retail pharmacy dispensing. In reporting their number of covered lives they may sum the lives covered in these two facets of operations, resulting in double counting of persons with overlap in these service components. Conceivably, some triple counting also might be possible, considering mail order prescriptions, claims processing, and formulary management activities that might be treated as separate functions by the PBMs and yield different clients and "covered lives." Similarly, the number of prescriptions may also have been subject to double or triple counting, as the number of prescriptions reported as managed by PBMs (1.6 billion) accounted for over three-quarters of the 2.1 billion prescriptions dispensed in 1995 (*Drug Topics*. March 4, 1996). *Drug Topics* reports that 1.07 billion prescriptions were paid by third parties.

Table III.5
Market Concentration

Covered Lives [a]	Number (Percent)
10 Million +	12 (16.7%)
5 - 9.999 Million	6 (8.3%)
1 - 4.999 Million	22 (30.6%)
< 1 Million	32 (44.4%)
Total	72 (100%)[a]
Concentration Ratios [b]	
4 Firm	44.4%
8 Firm	62.9%
20 Firm	87.5%[b]

[a] A total of 72 PBMs reported covered lives in either the MHC (1996) or BI (1995) directories

[b] Concentration ratios calculated based on the total covered lives reported by all PBMs in the MHC (1996)

Services Offered

Most PBMs reported a comprehensive set of services for clients. These services and the percent of PBMs reporting them is shown in Table III.6. Claims processing and maintaining a pharmacy network are not included in the table, since we consider them defining components of a PBM. It should be noted that any and all services might be subcontracted (with the possible exception of securing a pharmacy network) and the PBM providing a coordinating function. Several services are offered by nearly all PBMs, thus they could be interpreted as "core" capabilities of PBMs. It appears that PBMs recognize services as important components of their product, and they attempt to provide a range of services to meet competitive demands in their markets. The extent to which clients actually use services is not discernible from PBM-reported data in the directory surveys.

A survey of managed care providers by Emron (*CibaGeneva Pharmacy Benefit Report, 1996 Trends and Forecasts*) found that 84 percent of HMOs used PBMs for claims processing, 63 percent for rebate management, 49 percent for formulary management, and 59 percent for DUR. An Emron survey of employers found that 88 percent of employers offered mail-order pharmacy as a benefit for employees, primarily because employers believed it saved money, but also because of employee/retiree demand. A total of 44 percent of employers also reported they were implementing health/disease management programs.

Table III.6 Services Offered by PBMs

Services	Percent[a]
Prospective DUR	95%
Retrospective DUR	94%
Mail Order	92%
Prescription Card	88%
Point of Service Network	87%
Formulary - Open	76%
MD Compliance	75%
Wellness Programs	73%
Disease Management	72%
Capitation Programs or Risk Sharing	72%
Pharmacist Intervention Tracking	71%
Formulary - Restricted	65%
POS Network Linked to Medical Claims	61%
Outcomes/Pharmacoeconomic Research	61%
Payment for Cognitive Services	31%

[a] Percents based on number of firms reporting one or more service to clients (N = 89) in either the MHC (1996) or BI (1995) directories

Ownership

Both directories (MHC and BI) provided the name of the parent firm or owner of the PBMs. We categorized the PBMs into several owner category types, pharmaceutical manufacturer, MCO, retailer, etc. Our categorization was based upon name recognition and research team members' judgments; consequently, not all PBMs were categorized. A summary of PBMs by owner type is shown in Table III.7. The table includes aggregated number and percent of covered lives for each owner category and reflect a concentration of market share in pharmacy benefit managers, insurance industry, managed care organizations and manufacturers.

Table III.7
Ownership Type

Ownership Type [a]	Number of PBMs	Number of Covered Lives[b]	% Covered Lives [c]
Retailer	23	27,534,000	7.6%
Pharmacy Benefit Managers	8	74,350,000	20.6%
Insurance	7	38,500,000	10.7%
Managed Care Organization	6	46,900,000	13.0%
Home Care	4	3,260,000	1.0%
Manufacturer	4	129,300,000	35.8%
Other	2	15,007,000	4.2%
Wholesaler	1	5,000,000	1.4%
Unknown	33	20,314,325	5.6%
Total	89	360,810,325	100.0%

[a] Retailer = pharmacy chain, other retailer or group of retailers; PBM = independent PBM; Insurance = indemnity insurance industry; managed care organization = HMOs, PPOs and related health care organizations; Home Care = providers of home care services; Manufacturer = pharmaceutical manufacturer; Others includes Caremark (owned by a medical practice management and consulting company) and the Cystic Fibrosis Association; Wholesaler = Drug wholesaler or wholesaler group

[b] Number of covered lives reported by PBMs in the category

[c] Percent based on total number of covered lives reported by all PBMs reporting in the MHC (1996) or BI (1995) directories

IV. Literature Review on PBM Functions

To more fully develop concepts introduced in the preceding typology, the following section presents in-depth information on PBM administrative and drug use control functions. This information is based on available literature. Articles on PBMs are confined to the trade press and to newspapers, and much of the information is PBM-reported. For each PBM function, the authors review relevant peer-reviewed literature. Although most of these studies have not been conducted in PBM settings, the insights derived from such research can be applied to illuminate our thinking about their impact in PBM environments. For example, studies analyzing the effects of co-payments on vulnerable patient populations can inform our understanding of the possible impact of co-payments on Medicaid patients served by PBMs in managed care organizations.

Administrative Functions

1. Benefit Structure and Design

Included within benefit structure/design are issues of what drugs to be covered, exclusions, limits on coverage, and patient cost sharing requirements. PBMs can provide a standard benefit for clients to adopt (based on typical plans other clients use) or they can work with clients to design benefit parameters specific to client needs.

Drugs covered and decisions about them can be part of formulary decisions, but often prior to that, broad coverage and exclusion parameters are set. For example, "cosmetic drugs" or non-therapeutic drugs may be excluded. Some plans will exclude complete drug categories such as oral contraceptives or appetite suppressants. Coverage may be restricted to prescription drugs only, or to prescription drugs and selected nonprescription, over-the-counter (OTC) drugs.

Limits on Coverage

Limits on coverage often take the form of restrictions on the number of prescriptions or the amount of expenditures allowed during a specified time period (e.g., monthly). Establishing a limit on the number of prescriptions covered during a time period (month, usually, or a year) is an approach to limit or control costs. Patients needing additional prescriptions in excess of the specified limits are required to pay the entire cost of those prescriptions out-of-pocket. The extent to which these limits are employed by PBMs has not been reported in the trade and refereed literature. However, some state Medicaid programs have used this as an approach to contain costs.

Six states limit the number of prescriptions reimbursed per month by Medicaid, ranging from three to seven prescriptions per month (Pharmaceutical Benefits 1995). Under federal law, states must exempt children and nursing home residents from the monthly prescription limit.

Soumerai et al. (1987) reported that a Medicaid three prescription limit per month caused a sudden, sustained decrease in the overall number of prescriptions per patient per month (from 1.1 to 0.7) and that multiple-drug recipients were affected more severely by the limit (a decrease from 5.2 to 2.8 prescriptions per person). A follow-up study showed the prescription limit was associated with an increased risk of institutionalization in nursing homes (Soumerai et al. 1991).

Soumerai et al.(1994) also examined the effects of this three-prescription monthly payment limit on the use of psychotropic drugs and acute mental health care by noninstitutionalized patients with schizophrenia. The policy resulted in immediate reductions in the use of antipsychotic drugs, antidepressants and lithium, and anxiolytic and hypnotic drugs. It also resulted in coincident increases in visits per patient per month to mental health clinics and an increase in the use of emergency mental health. After the limit was discontinued, the use of medications and most mental health services reverted to base-line levels.

These studies suggest that limiting access to drugs by imposing arbitrary limits in the number of prescriptions may have unintended and detrimental effects on health care costs and utilization outweighing the savings from reduced use due to the limits.

Cost Sharing

Patient cost sharing requirements are means by which drug program administrators/managers attempt to exert some cost containment pressure on patients by making them at least somewhat sensitive to the cost of the benefit they receive. Several cost sharing approaches are possible and have been used in prescription drug programs.

Deductibles have been used in some programs, particularly indemnity-type plans. When a deductible cost sharing requirement is present, patients pay for any and all prescriptions and services up to a predetermined total dollar amount. Once that level of accumulated patient spending has been reached, drug program coverage begins.

Co-payments and co-insurance provisions operate as deductibles on a per service unit basis rather than on an accumulated basis. For each service used (prescription dispensed), the patient is responsible for a portion of the cost, either as a fixed amount for each prescription dispensed (co-payment) or as a percentage of the prescription cost or charge (co-insurance). In service benefit prescription drug programs, co-payments have been most common, in part because the amount patients will be required to pay per

prescription can be specified with certainty in advance. This predictability and certainty in out-of-pocket cost for beneficiaries traditionally has been important to, and accepted favorably by, employees when negotiating the benefit component of their employment compensation packages. Unfortunately, it does not reflect as directly the costs of resources used in obtaining/providing the services as a co-insurance cost share does.

PBMs can (and do) employ any or all of these cost sharing mechanisms, deductibles, co-insurance, or co-payments, individually or in combination, to meet needs and desires of clients with whom they contract. Often, these cost sharing provisions are adjusted to facilitate or enhance drug use management initiatives PBMs may implement. For example, differential (lower) co-payment amounts or co-insurance rates can be used for formulary preferred or generic drugs to divert patient demand to lower cost agents.

Payers encourage the use of generics by patients by establishing a higher co-payment for brand name products than generic, or by limiting reimbursement to an amount equal to the generic cost of the drug. A 1994 report of drug programs in HMOs showed 87 percent of HMOs permit members to chose brand-name over generic drugs and 73 percent of these HMOs require members to pay the difference in cost between the brand and generic version of the drug. Another 34 percent of HMOs require members to pay a higher co-payment for choosing the brand-name drug. (Marion Merrell Dow 1994). A 1996 survey of HMOs reported an average co-payment of $4.56 for brand name drugs and $2.39 for generic drugs (*Trends and Forecasts Surveys 1996*, Emron Inc.).

In most states, Medicaid coverage is limited to the cost of generic versions of most drugs available as multi-source products. Thirty states have co-payments for Medicaid prescriptions (Pharmaceutical Benefits 1995). The co-payments ranged from $.50 to $3.00 per prescription. Federal Regulations (42 CFR 447.54) restrict co-payments to $.50 for services costing $10 or less and to a $3.00 co-payment for services cost over $50. The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) prohibits states from imposing cost-sharing on services furnished to individuals under 18, pregnancy related services, services provided to institutionalized individuals, family planning services and services provided to categorically needy HMO enrollees.

Medicaid restricts the options of recipients to seek brand name or non-formulary drugs by requiring the prescriber to certify these drugs as medically necessary. As a result, Medicaid does not utilize a lower co-payment for generic or formulary drug use.

Although the use of cost sharing mechanisms is common among PBMs, evaluations specific to PBMs of the impact of these cost sharing provisions have not been reported in the literature. However, investigations of cost sharing provisions in public and private drug programs have been reported. Soumerai et al. (1987) reported co-payments did not change the number of prescriptions received per Medicaid recipient. However, Medicaid costs did decrease as the result of cost shift to recipient. A subsequent study identified an increase in nursing home use associated with the change in co-payment (Soumerai et al. 1991).

In addition to the above studies, two co-payment studies, each with follow-up analyses showed reductions (7 to 11 percent) in numbers of prescriptions obtained by Medicaid recipients (Nelson, Reeder, Dickson 1984; Brian and Gibbons 1974). Subsequent studies confirmed decreased expenditures for drugs, but raised questions about whether other expenditures may have increased due to failure to apply preventive (drug) care for hypertension, heart conditions, and other disease categories where drug use decreased (Reeder and Nelson 1985; Roemer et al. 1975). These studies were included in a review of the literature on co-payments and prescription limits in Medicaid programs (Soumerai et al. 1993).

Smith (1993) studied drug use and costs of employer groups when the drug co-payment was changed from $3 to $5. The increase in co-payment amount was associated with a 5 percent decrease in number of prescriptions, and offsetting increase in ingredient cost per prescription. While there was a savings for the employer, the employee had an increase in cost. Harris, et al.(1990) found that co-payments were associated with lower per capita costs and higher per prescription unit costs. In this HMO population, the decrease was greatest for discretionary drugs (analgesics, nonsteroidal anti-inflammatory drugs, cough and cold products, and skeletal muscle relaxants).

A recent study of cost containment strategies in HMOs examined the impact of average annual drug co-payment on resource utilization variables including hospital admissions, emergency department visits, physician visits, and prescription counts and costs across five disease groups (Horn et al. 1996). In 24 of 35 regression equations, drug co-payment was not significantly associated with resource utilization and 10 of 11 equations where co-payment was significant, it was positively associated (higher co-pays were associated with greater utilization). The specific effects of prescription co-payments on prescription utilization or cost were not reported, either as regression results or binomial correlations, thus insights into this benefit structure parameter were not available from this study.

Mail Order Services

Our typology shows nearly all PBMs offer mail order prescription services to clients. *Business Insurance* reported the percent of prescription volume dispensed through mail service pharmacies has considerable variability. Most PBMs reported percents of 25 percent or less of their prescription volume dispensed through mail order. The range of mail order prescriptions is from 0.2 percent for Claimspro Health Claims Services, Inc. to 100 percent for Certifax Pharmacy Services (*Business Insurance* 1996).

The pharmacy trade press reveals a trend in PBMs purchasing mail order pharmacies or developing in-house mail order capabilities ("DPS Buys Mail-Order Pharmacy" 6 March 1995; Muirhead 8 July 1996). The goal is to give PBMs more control over cost and services, eliminate a "middle man," and help ensure mail and retail

data are enveloped into one integrated system. There also appears to be a trend toward developing new services to be offered through or in conjunction with the mail order component of PBMs' businesses (Slezak Dec 1995; Gebhart 21 Aug 1995; Muirhead 10 June 1996). Mail order companies as subsidiaries or potential subcontractors to PBMs are developing and implementing disease management, outcomes management, patient counseling, therapeutic interchange initiatives, and integrated data management services.

Since mail order pharmacies compete with community retail pharmacies for dispensing prescriptions, there is considerable controversy about the role of mail order pharmacies and their costs. General market trends over the last decade have shown growth in sales and the number of prescriptions dispensed for mail order pharmacies. Mail order has been promoted as a convenient and lower cost channel for consumers to obtain their prescriptions, particularly for maintenance medications. Mail order pharmacies claim cost advantages related to differences in generic dispensing rates, prescription dispensing production function economies, purchase volume-related acquisition cost differences, and larger dispensing quantities (yielding fewer pharmacy margins for dispensing fees and/or patient co-payments).

The literature on mail service pharmacy is limited to the extent that few empirical studies comparing costs and quality of mail and retail pharmacy providers are reported. Inherent difficulties in evaluating mail services pharmacies include the proprietary nature of data, funding sources, data variability across providers, and cost measurement differences. Most information is gleaned from trade press mentions of proprietary reports or anecdotal experiences with mail service pharmacies. It is difficult to evaluate the rigor of methods or derivations of estimates in these typically cryptic reports. The bulk of this literature suggests mail service pharmacies may represent potential savings, but conflicting reports also are present. For example, a Booz-Allen and Hamilton survey of employer and provider PBM programs found mail order brand and generic prescriptions cost an average of AWP less 13% and AWP less 33% respectively, compared with AWP less 2% and AWP less 4% for brand and generic prescriptions in community pharmacies. They based these estimates on assumptions of brand name mail prescriptions having an average cost of $75, mail generic average cost of $25 and community pharmacy brand and generic prescription average costs of $30 and $10, reflecting differences in quantities of drugs dispensed. ("Mail Order Branded Scripts Cost AWP-13%" 6 November 1995)

In 1989, HCFA commissioned a study to evaluate the use of mail service pharmacies (Horgan et al. 1989). Although the overall conclusion from the study was that estimated averaged charges per day supply for mail service pharmacies did not appear to be substantially different from that for retail pharmacies, the study was challenged and largely discredited by the mail service pharmacy industry. The results were very sensitive to assumptions about average prescription prices and average prescription days supply in the retail pharmacy sector, and the amounts selected for use in the analysis were criticized because they yielded favorable estimates for retail pharmacies.

Difficulties in conducting rigorous evaluative studies and politically charged perspectives continue to date. Consequently, there is a lack of empirical research evaluating cost or quality of mail service pharmacies relative to community pharmacies. Any conclusions relative to cost or quality differences would be tentative at best.

The growth and market success of mail service into PBMs' product offerings suggest there must be some real or perceived cost, convenience, quality, or other advantageous characteristic difference that consumers and/or purchasers recognize.

2. Pharmacy Network

Since PBMs primarily function as benefit managers and not providers, they rely on community pharmacies to provide prescriptions to clients' drug program beneficiaries (except for prescriptions dispensed through in-house mail service operations). The pharmacies that provide services on behalf of the PBMs are referred to as provider panels or networks. Pharmacists sign contracts with PBMs agreeing that their pharmacy will serve as provider to individuals covered under prescription drug programs that the PBMs administer. These contracts can vary, a PBM may have different prices it will pay to pharmacies for different clients' plans. The contracts between pharmacies and a PBM ensure pharmacies will have access to PBM-covered drug program individuals, and vice versa.

The rates PBMs can charge to clients are influenced by rates PBMs pay providers. Since PBMs can represent considerable numbers of patients to a pharmacy they may be contracting with, traditional price-volume trade-offs can be present in payment offers or negotiations PBMs have with pharmacies. If PBM contracts can be restricted to limited numbers of providers, corresponding discounted prices may be obtained from those participating providers. However, in many states there are legislative barriers that decrease the prospects for PBMs to take advantage of possible price-volume trade-offs markets may allow. A total of 31 states have enacted "any willing provider" legislation to preclude PBM (and other such entities') efforts to restrict numbers or types of pharmacies that participate as providers (Pharmaceutical Benefits 1995). Under such legislation, any and all pharmacies willing to agree to PBM contract terms (both price/payment to the pharmacy, and, to a lesser extent, performance requirements) must be allowed to be a participating provider.

The price PBMs offer to pharmacies (payment rates) and participation are connected with a PBM's ability to serve clients (and potentially the price they can charge clients), sometimes in a precarious balance. This phenomenon was demonstrated in late 1995 when pharmacies refused to participate because of payment terms offered by a PBM for a State employee drug program, causing the PBM contract with the state to be re-bid. (Slezak 1996; *Weekly Pharmacy Reports - The Green Sheet.* 1 Jan 96). Secondarily, the PBM sued the nonparticipating pharmacies, alleging they conspired to boycott (Conlan 4

March 1996). Such a sequence of events reflects the complexity of maintaining pharmacy panels and participation.

Most PBMs have wide geographic distribution of pharmacies by virtue of their national panels. PBMs use computer zip code analysis to ensure participating pharmacies are within a desired distance radius. For PBM plan enrollees in rural areas, a 5 mile radius typically is used to gauge access; in urban areas a more restricted distance of 0.5 to 1 mile radius is used. A sample of a PBM's panel description showing access breakdown across the PBM's pharmacy panel is included in Appendix C. This access parameter of distance to a participating pharmacy can be compromised with restricted networks.

Drug Use Control Functions

1. Formularies and Formulary-Related Activities

In its most basic definition, a formulary is a list of drug products. As the nature and functions of the formulary have grown more complex, so has the attendant definition of the term. Navarro and Wertheimer (1996) define formularies as lists containing drug products that are preferred for use by payers (e.g., insurers and managed care organizations) and are dispensed through participating pharmacies to covered persons. There are three types of formularies, and each of them will be described briefly.

Open (or unrestricted) Formulary:

This type of formulary includes all (or nearly all) drugs and drug products. Non-therapeutic drugs, ineffective or unsafe drugs, or drugs that make people "better than well" are examples of drugs that might be excluded from coverage, yielding a minimal amount of formulary restrictiveness.

Closed (or restricted) Formulary:

A closed formulary is a limited list of drugs approved for use or covered under the drug plan. With a closed formulary, some drugs are not covered, or, in the traditional hospital formulary scenario, are not stocked by the pharmacy and not available for use within the institution.

Formularies vary in strictness, from narrowly restricted (with very limited choices of drug agents available or covered within a therapeutic class) to completely open (with all drugs available and covered).

"Managed" Formulary:

A companion issue with PBM formularies is the notion of steerage to preferred products via incentives that direct product use. Open formularies that have "preferred

products" and incentives to increase utilization of these drugs might be labeled "managed" formularies. PBMs and their clients often benefit financially from the use of preferred products via rebates from manufacturers and reduced drug costs. Sometimes managed formularies incorrectly are referred to as "restrictive formularies" because the incentives for patients to use preferred drugs appear as financial limits ("restrictions") in coverage. For example, a managed formulary may cover the cost of a generic drug, but if the branded product is dispensed, the patient must pay the difference in drug cost. Another common incentive requires the patient to pay a higher co-payment for a non-preferred drug.

The concept and use of "formulary" within the PBM environment implies a restriction on available drugs, as with the historic example of formularies in hospitals. However, "managed" rather than "restrictive" is a better descriptor of most PBM formularies because they focus on incentives to direct use to preferred products, rather than the exclusion of drugs from coverage. Some PBMs offer closed (or restricted) formularies for specific clients, particularly managed care organizations.

Formularies as Drivers of PBM Drug Management Activities

Formularies provide overarching program structure for the drug benefit because they define which drugs can be used. Specific drug management activities are engaged within this overarching structure:

Prior authorization is a mechanism to restrict the use of services by requiring pharmacies to obtain advance approval before dispensing certain drugs (Smalley et al. 1995). It is a way to allow access to drugs not included on the formulary because of cost or therapeutic reasons. Prior authorization serves as a "gatekeeping" function, that is, access to newer or more high-cost medications (e.g., growth hormone) or drugs with indications outside the scope of benefits (e.g, Retin A) cannot be granted unless the prior authorization process is undertaken and approval is given.

Interchange programs (see section on Interchange Programs) helps direct drug use to generic drugs (generic substitution) and formulary products (therapeutic interchange). The use of formulary drugs benefits financially the PBM and its client, either because bona fide cost effectiveness analyses have been completed (rare) or because rebates or other financial arrangements associated with a given product provide cost advantages. Differential patient co-payments or pharmacist dispensing fees for generic and preferred products encourage formulary compliance, which may result in program cost savings and sometimes therapeutic advantages for patients.

Drug utilization review (DUR) (see section on DUR) occurs within the program formulary. DUR interventions change patterns of drug use where problems from potential adverse effects (interactions, side effects, under or over dosing, etc.) yield less than optimal therapy or when less cost-effective use patterns are revealed (again

related to bona fide cost effectiveness differentials, or financial arrangements influencing the cost effectiveness profile).

Disease management (see section on Disease Management) in the PBM environment can be viewed as a drug use control activity that focuses on directing drug use and patient behaviors to minimize the total cost of illness and improve medical and pharmaceutical care.

Review of the Trade Literature --
Formularies, PBMs, And Formulary-Related Drug Management Activities

Some general information exists in the trade press relative to PBM formularies and how they are used. Several articles focused on Pharmacy Gold as a PBM specializing in formulary management. Pharmacy Gold is a subsidiary of Blue Cross Blue Shield of Minnesota that contracts with managed care organizations and other PBMs to develop and administer formulary management plans (*Drug Topics*. September 5, 1994:78). Pharmacy Gold first developed as a firm to serve the needs of its parent company and later became a separate company to attract business from other health plans (Muirhead 1994). Its Pharmacy and Therapeutics (P&T) committee is typical of PBM P&T committees and includes physicians, pharmacists. Some client representatives may attend P&T committee meetings and offer input. The P&T committee evaluates drugs for formulary status on therapeutic value, side effects, comparisons with other drugs on the formulary, and cost. Health plans or other PBMs may use Pharmacy Gold's formulary to avoid start-up time and costs, to eliminate the effort needed to create a formulary, to avoid personnel and administrative costs of managing their own formulary, and to achieve collective leverage for volume purchasing and price rebates in negotiations with pharmaceutical manufacturers.

PBM strategies to involve patients and physicians in formulary compliance are varied and involve increase reliance on electronic technology and computerized feedback. While some PBMs provide patients with "formulary cards" listing preferred drugs to take with them to physician office visits, PCS has developed electronic linkage systems with physicians to provide formulary information and patient drug utilization information for use in prescribing decisions made in their office settings (*American Druggist*. January 1996:1). Another PBM, Prescription Solutions, has posted its formulary on the Internet for use by physicians of patients enrolled in its managed care organization, Pacificare (*Managed Pharmaceutical Report*. July 1996:6). A health technology firm has developed an "electronic formulary" -- a pocket-sized reference guide that includes a health plan's entire formulary and lists the relative cost of drugs, therapeutic class, and condensed versions of the approved product labeling. Physicians selecting non-formulary agents are directed to formulary drugs via warning messages when less costly alternatives are available (*Weekly Pharmacy Reports - The Green Sheet*. March 11, 1996:4).

Typically, formularies are important in contract negotiations between PBMs and manufacturers for rebates. Higher discounts or rebates can be realized when large volume of drugs are purchased by PBM clients. Some manufacturers are developing more stringent rebate contracts with PBMs which require shifts in product market share. Manufacturers and PBMs believe that shifts in market share result from formulary restrictions or more aggressive incentives for preferred product use under managed or closed formularies (Muirhead 1994). For example, early in 1995, Merck discontinued discounts and rebates for PBMs with open formularies, but continued rebates for PBMs that included Merck products on closed or managed formularies (*The Pink Sheet*. February 20 1995:T&G-9.) When brand-name drugs lose patent protection, PBM formularies usually convert the generic version to formulary status. In rare instances, branded product manufacturers may provide pricing incentives making the branded product more competitive than the generic product (Epstein 1995).

Because of their central role in the dispensing process, pharmacists play a vital role in formulary compliance. Pharmacists express dissatisfaction because they are increasingly being asked by PBMs to enforce formularies by contacting physicians and asking them to adhere to formulary guidelines, but they often receive no or limited remuneration for these time-consuming and labor-intensive tasks. Further, pharmacists also struggle with the problem of formulary differences across PBMs that create confusion in the physician community and bring complaints from patients when they change PBMs and their drug covered is also changed (Muirhead (b) 1994). However, some PBMs have developed programs to incentivize pharmacists for enforcing formularies. These programs pay pharmacists fixed amounts or shared savings amounts based on the difference in cost between the prescribed and formulary product. National Prescription Administrators, a medium-sized PBM based in New Jersey, has reported that community pharmacists are successful 5 to 15 percent of the time when calling physicians to change prescriptions (Muirhead 1995). PCS has reported that about 30 percent of total prescriptions written under the program are successfully switched (*Managed Pharmaceutical Report*. June 1996:5).

Many PBMs assert that their formulary management activities have been successful in moving volume and/or market share. Express Scripts PBM reported switch rates of 55 percent for H_2 antagonists and antihyperlipidemics (55 percent and 59 percent savings, respectively), 74 percent for ACE inhibitors (32 percent savings), 81 percent for calcium channel blockers (33 percent savings) and 95 percent for inhaled steroids (10 percent savings). It also claimed a higher generic dispensing rate than any other PBM, including about 30 percent in the H2 antagonist drug class *(Weekly Pharmacy Reports - The Green Sheet*. January 22, 1996:4) In its mail order business, the PBM asserts that it intervenes on one third of all prescriptions and is able to reduce the cost for 10 percent of all prescriptions received by an average of $68.00. Merck-Medco reported an overall 51 percent brand-to-brand switch rate and 73 percent brand-to-generic switch rate with its mail service interventions (*Weekly Pharmacy Reports - The Green Sheet*. December 18, 1995:2).

Some formulary management activities have encountered criticism. For example, investigations in 17 states against Merck resulted from allegations that some of the switch programs violated consumer laws by failing to disclose pertinent information when Medco pharmacists called physicians about switching a prescription drug. Under the terms of a voluntary agreement between Merck/Medco and 17 states, Merck, while admitting no wrong doing, agreed to pay each state $115,000 to cover costs of investigation, and agreed to disclose to doctors that the pharmacist is calling on behalf of Merck and to disclose the name of the maker of the drug the pharmacist is recommending (Conlan 1995; Slezak 1995). Although there is consensus that switches to generic drug products and pharmacist reimbursement for such changes are acceptable, there is growing concern about brand-to-generic switches when the drugs have narrow therapeutic indices and pharmacists or patients are pressured to use them (Ukens 1995). Finally, there is concern when the drugs are not equivalent (as, for example, in therapeutic interchange), or when switches are based primarily on financial factors rather than on patient care considerations (Gebhart 1995).

Concern about the relationship between financial incentives and patient care considerations may escalate, since several PBMs (e.g., PCS and First Health) are developing and/or enhancing programs targeted toward pharmacists with the goal of decreasing program costs. These programs incentivize pharmacists by paying them extra amounts if they effectively enforce a closed formulary, increase their percentage of generics dispensed, or meet other cost-saving targets (Muirhead 1994; Beavers 1995).

Another strategy intended to increase use of preferred formulary drugs is academic detailing. The trade press reports that WellPoint and PCS have used PBM-employed pharmacists to telephone or visit targeted physicians to discuss prescribing behavior and reasons for prescribing preferred drugs. The PBMs' academic detailing or "counterdetailing" efforts may be bolstered in the future by partnering with drug manufacturers' sales forces (Muirhead 1996; *Weekly Pharmacy Reports - The Green Sheet* June 3, 1996:1).

The potential connection between PBM ownership by pharmaceutical manufacturers and preferred formulary status for those firms' products has drawn the attention of competing, non-vertically integrated pharmaceutical firms, and has raised governmental concerns about possible antitrust implications. A recent GAO analysis revealed formulary changes that might have benefited the parent firm by reducing competition for their products. However, the evidence did not demonstrate that preference was given to the parent firm's product without considering competitors' products. The study concluded that continued FTC monitoring for potential anti-competitive activity associated with preferred formulary status for manufacturer-owned PBM parent firms' products was warranted (GAO 1995).

Rebate Connection and Changes in Rebating

Since formularies and formulary-related drug use management activities influence which drug products are dispensed, financial arrangements associated with moving market share usually are connected with formularies. Rebates from manufacturers to PBMs are the most common mechanisms to recognize movement in product market share. Rebate arrangements also are a critical factor determining relative costs of similar, competing products within therapeutic groups.

In the context of PBMs, rebates parallel price discounts offered to hospital purchasers and health plans agreeing to assign formulary status to a selected drug product or limited numbers of drugs in therapeutic categories and exclude other products from their inventories. With the exception of their mail order operations, PBMs do not take possession of drug product (nor do Medicaid programs). However, they may influence drug use through benefit design changes and drug use control mechanisms; therefore, their financial arrangements with manufacturers are formulated as rebates for product movement rather than as discounts on goods purchased.

The ability of a PBM to influence drug use through changes in benefit structure and drug management policies has vested them with leverage to seek and negotiate rebates from manufacturers. Originally, rebates were provided based on the volume of sales associated with PBMs. However, OBRA '90 requires manufacturers to provide Medicaid programs with the best price they offer other buyers (in the form of rebates), and volume discounts alone do not ensure shifts in market share relative to competitors' products. For these reasons, rebate arrangements usually now require market share changes as qualifications for receiving a rebate. Some firms are de-emphasizing rebate arrangements and either moving away from them or complementing them with "value added" programs, such as compliance or education programs (Epstein 1996). Conceivably, PBMs may benefit financially from these arrangements, since they might not be revealed and "shared" with clients, unlike rebate dollars, of which clients often demand a large share.

Peer-Reviewed Literature on Formularies

The peer-reviewed research literature evaluating the impact of formularies and other administrative restrictions (e.g., prior authorization) in the community pharmacy arena is inconclusive and somewhat controversial, largely because the findings are inconsistent and most studies are poorly controlled. Proponents of administrative restrictions contend that formularies achieve cost savings because more cost-effective drug products are used instead of newer, unproven, and more expensive products. The counter argument is that failure to cover selected drugs can lead to unintended reductions in quality of care and increased costs due to the use of sub-optimal products, the exacerbation of disease or symptoms, substitution of more expensive drug products, or substitution of other, more expensive services, such as physician and hospital services.

No studies specific to PBM formularies are available, and studies in private third-party drug programs (common PBM precursors) are scarce; most research has focused on Medicaid populations. Jang (1989) conducted a literature review of restricted formularies in Medicaid programs. He concluded that when the total drug budget or total Medicaid program expenditures are considered, restricted formularies do not achieve savings and potentially lead to diminution in quality of care.

Soumerai et al. (1993) critically analyzed studies evaluating administrative restrictions in State Medicaid programs that limit clinicians' abilities to prescribe particular medications, including formularies, category exclusions, or prior authorization requests. Their review covered much of the same literature as Jang, but more carefully and systematically assessed the rigor of research methods used in the studies to focus on potential sources of bias or imprecision in study results or conclusions. They found a high prevalence (83 percent of reviewed studies) of inadequate research designs -- typically, inadequately controlled studies -- suggesting that the conclusions of formulary and drug exclusion studies may be suspect. Their evaluation concluded there is evidence of both positive and negative effects depending on the types of drugs involved, and they encouraged more rigorous design and more careful examination of first order effects (substituted drugs) and second order effects (substitution of other health services) in future studies. They suggested the high prevalence of inadequate designs may be explained because most studies were privately funded by pharmaceutical manufacturers and did not undergo formal peer review at the proposal or dissemination stage.

Several studies have been published since these reviews, some with favorable results, e.g., cost savings, associated with a formulary or prescribing restrictions. Most studies would be subject to the same criticisms as the Medicaid studies reviewed by Soumerai due to design difficulties, or inadequate consideration of substitution or second-order effects.

A study in the California Medicaid program raised the question of whether treatment protocols may be viable alternatives to restrictive formularies and prior authorization for high-risk patients (McCombs and Nichol 1993). In this study, appropriate use and access to a high cost cephalosporin antibiotic was estimated to reduce post-treatment costs.

A physician practice in Scotland implemented a "generic formulary" intended to stimulate generic drug use (Dowell, et al. 1995). The study reported success in increasing generic prescribing and reduced costs that was "tolerated" by the patients; a full 20 percent of mail-surveyed patients were "very unhappy with changes," although interviews suggested this dissatisfaction was primarily with the communication they received rather than the change in drug therapy.

An anti-ulcer formulary prescribing program developed as a result of DUR was implemented in the pharmacy program of a Texas correctional system (Keith, et al. 1994). The program was designed to reduce anti-ulcer agent dosages by applying therapeutic

guidelines as a type of formulary intervention. Mean daily dosages, duration of therapies, percents of patients with potentially significant drug interactions, and dosage units dispensed per month all decreased, resulting in a projected annual savings with no identifiable clinically important changes in use of antacid products or prescribing of upper gastrointestinal examinations. The authors concluded the program helped optimize anti-ulcer prescribing and use, with no discernible unfavorable effects on patient care.

Yakabowich et al. (1994) studied drug use in nursing homes after implementing a formulary and found adherence to the formulary predicted homes with decreased drug expenditures. Expenditures for specific agents and drug classes targeted as being inappropriate for long-term care decreased because of reduced prescribing, but expenditures for some other drug classes increased because newer, more expensive agents were used. They concluded that a formulary can improve therapeutic management and the impact on cost containment was not as strong after the first year, although expenditure changes were less than the rate of inflation for drug costs.

Results from another study raised questions about the role of formularies in reducing drug costs (Anis 1994). The analysis focused on factors associated with generic drug use in Canada. The researchers concluded that formularies were not significant determinants of product substitution. Other variables such as legal liability, mandated product selection, and deductibles and co-payment levels were better predictors of drug substitution. The results were derived from regression models incorporating aggregate measures of drug use and generic dispensing across Canadian provinces.

A recent study examined the impact of levels of formulary strictness on use and costs of drugs and health care services in six health maintenance organizations (Horn, et al. 1996). The researchers analyzed these outcomes for patients having one or more of five diseases (arthritis, asthma, epigastric pain/ulcer, hypertension, otitis media). The authors attempted to control for patient characteristics and severity of illness via patient-level analyses. The authors concluded that their analyses demonstrated that "more restrictive formularies" were associated with higher prescription drug use and drug costs, as well as increased office visits, emergency department visits, and hospitalizations per patient per year.

Unfortunately, serious methodological shortcomings limit the interpretation of study findings. For example, the analyses did not examine formulary restrictiveness within drug classes for the selected five diseases and link such restrictiveness with number of prescriptions and drug costs and other utilization variables for disease-specific changes.

Interestingly, the average drug co-payment paid by a patient over the course of a year was either not significantly or positively associated with resource utilization dependent variables (higher co-payments were associated with greater utilization), but visit co-payments were significantly associated with lower utilization of drugs and drug costs. The specific effects of prescription co-payments on prescription use or costs were

not reported, either as regression results or binomial correlations; thus, insights in the effects of co-payments were not available from this study.

As noted by Ross-Degnan and Soumerai, the study fails to control for pre-existing differences among the HMOs in patterns of care, populations, and administrative policies (Source: Dennis Ross-Degnan and Stephen B. Soumerai, "HMO formularies and care costs," *Lancet (*correspondence, Vol. 347, May 4, 1966, p. 1264.) Further, the study design was cross sectional; data were collected prospectively but over a limited period of time. Thus, a causal link between the strictness of the formularies and higher health care costs could not be established through this study design.

2. Prior Authorization

As a mechanism for obtaining permission to prescribe a drug, prior authorization implies formulary restrictions are present, but exceptions are possible. Exceptions can be allowed via a preapproval process. The burden of the preapproval process and risk that approval be denied may provide a disincentive for prescribing and use of restricted drugs; further, the "hassle factor" involved in going through the process may divert physicians' attention from more important clinical activities (Soumerai and Lipton, 1995). Theoretically, prior authorization provides a mechanism to target costly, limited use, new, and/or potentially toxic drugs only to patients that truly need them and limits their use where less expensive or safer alternatives could be used.

Prior authorization programs have been present in public (and likely private) drug programs since at least 1980 (Soumerai, et al. 1993). However, only a limited number of evaluations have been completed of prior authorization as a cost saving or quality enhancing mechanism. OBRA '90 stimulated prior authorization activity in Medicaid programs because it required states to cover nearly all pharmaceuticals but permitted prior authorization as a means to foster appropriate use of high cost drugs, drugs with narrow therapeutic indications, or drugs with high abuse potential. Since OBRA '90, two similar evaluations of prior authorization programs have appeared in the literature.

In 1990, a prior authorization program for single-source NSAID agents was initiated in the Georgia Medicaid program. An evaluation based on time series analysis during the first seven months after the start of the prior authorization program showed a decrease of more than $3 million for the 80,064 recipients that had received one or more NSAID agents during the study period and the previous year (Kotzan, et al. 1993). A time series analysis revealed approximately 50 percent of the single-source products were displaced by multi-source generic agents. The decrease in cost was offset partially by increased utilization of non-narcotic analgesic agents, but no additional medical or physician costs were observed. Although costs of administering the program were not included in the analysis, the authors doubted the inclusion of such variables would change the conclusion since expenses for the program management division responsible for administering the drug program decreased.

The same prior authorization requirement was implemented in Tennessee at the same time (Smalley, et al. 1995). An interrupted time series analysis showed expenditures decreased by 53 percent during the two years after the prior authorization requirement, yielding an estimated savings of 12.8 percent compared to the experience in the previous baseline year. Their analysis also showed minimal or no increases in the use of other analgesic and anti-inflammatory drugs or other medical services, and they claimed low administrative costs for the program (although they were not quantified or included in the analyses).

Both these studies showed prior authorization programs successfully reduced expenditures. Kotzan, et al. (1993) noted that the prior authorization program for single-source NSAID prescriptions may have been more successful than other formulary restriction evaluations reported in the literature for several reasons. First, the policy targeted drugs that, in general, were expensive, and thus alternate therapeutic agents would be less expensive. Second, the probable patient population affected, arthritic patients, likely would not seek emergency or institutional care as a substitute for single-source NSAID therapy. Also, the therapeutic advantages of the prior authorized (single-source) drugs over the alternate (multi-source) drugs may not have been sufficient for recipients to insist on the single-source, prior authorized drugs. Whether these conditions (less expensive alternates, low probability of substitute care, and low resistance to the desired changes) might be applicable to drugs in other therapeutic categories with prior authorization requirements and yield similar success will remain a question for speculation until additional research is conducted.

3. Drug Utilization Review (DUR)

Drug utilization review (DUR) is a structured, ongoing program that interprets patterns of drug use in relation to predetermined criteria and attempts to prevent or minimize inappropriate prescribing (Lipton, Bird 1991; Rucker 1983; Soumerai, Lipton 1995).[10] Thus, it resembles other utilization management programs reviewing the appropriateness and costs of medical procedures, including surgery and hospital admissions. DUR may be conducted retrospectively or prospectively, and OBRA '90 mandated both types (*Public Law 101-508* November 1990). A prospective review is designed to enable pharmacists to detect potential problems with drug therapy before they dispense medications. Currently, most pharmacists in the United States provide such a review on site: they maintain histories of their customers' prescriptions, often using computerized screening systems unique to their own pharmacies. A GAO report (1994) estimated that by the end of 1995, about half of the states' Medicaid programs would have prospective DUR programs on line (General Accounting Office 1994). Effective April, 1996, 29 states' Medicaid programs operated P-DUR systems on line (General Accounting Office 1996). These programs use standardized software to detect potential drug-therapy problems and have access to centralized information about a patient's

[10] Much of the subsequent discussion and literature review is drawn from Soumerai and Lipton, 1995.

prescription history, regardless of where the patient purchased the medication. In the private industry, this is considered to be a standard service provided in PBM programs.

OBRA '90 requires that DUR criteria be developed to identify problems in certain categories, including inappropriate dosage, overuse (e.g., early refills), underuse (e.g., late refills), duration of therapy, duplication of therapy, indications or contraindications, and interactions between drugs. These criteria have to be drawn from drug compendiums specified in the 1990 legislation or from the peer-reviewed literature. If the patient's prescription violates the criteria, the pharmacist is required to determine (sometimes by calling the prescribing physician) whether to dispense it as written, to adjust the prescription, or to dispense no prescription.

Retrospective drug-utilization review, which is conducted after medications are dispensed, usually checks claims data to identify potentially inappropriate prescriptions for individual patients. If the computer program finds that a physician's prescription for a particular patient has violated the criteria for optimal drug use, the case is reviewed by a panel of physicians and pharmacists. If the panel finds the prescription problematic, it sends an advisory letter asking the physician to change it.

All Medicaid programs nationwide are now engaged in either retrospective or prospective reviews of this type, and the majority are performing both. At least half the retrospective programs are operated by private firms. In the private sector, the prescriptions of an estimated 75 percent of Americans with outpatient drug insurance are scrutinized (Walser 1994).

From their inception, most PBMs developed and are using P-DUR and R-DUR services in both the private and public sectors (see Typology section). Some have reported encouraging results. For example, Intell-rx, the subsidiary of PBM Eagle Managed Care, conducted a pilot DUR intervention in Pennsylvania's PACE program[11] between 1993 and 1994. The DUR intervention involved pharmacists contacting physician "outliers" (identified by pharmacists using a proprietary computer software program) and meeting with or telephoning them to recommend alternative therapies to decrease drug costs and improve medical care. Intell-rx then examined subsequent prescribing practices, and it analyzed savings separately for drug costs and for potential drug-related medical costs, based on probabilities of patients experiencing certain complications and incurring associated costs (*Managed Pharmaceutical Report*. February 1995:8). The researchers found that the DUR program saved an average of $29,000 in each of the four months of program operations and projected that if the pilot project had included all 350,000 patients in the PACE program, savings could have exceeded $3 million for the year. Although these results sound promising, they have not been published in peer-reviewed journals, thus precluding scrutiny of the rigor of study design and methodology.

---

11 Pennsylvania's PACE (Pennsylvania's Pharmaceutical Assistance Contract for the Elderly) is the nation's largest state-supported pharmaceutical assistance program for low-income senior citizens who do not qualify for Medicaid coverage.

Claims that DUR in the ambulatory arena is cost effective because it reduces the incidence of drug-related illness and hospitalization tend to be inflated and based on unpublished, poorly controlled, or biased studies (LeGrady 1992; *Issues Answers*. 1990:4). Few evaluations of commercial programs have been published (Soumerai, Ross-Degnan 1990), because of the proprietary nature of the programs (Lipton, Bird 1993). Typically, retrospective studies have merely determined how often problematic drugs are discontinued, often months after physicians have received a peer-review letter. These studies measure success by the percentage of cases in which drug-therapy decisions are altered (Groves 1985), but they do not explore other possible explanations (e.g., that physicians may have changed their prescribing behavior before the peer-review letter was sent) (Lipton, Bird 1991). These weak research designs suffer from many biases, including regression to the mean, which tends to exaggerate the effects of the review program (Soumerai, et al. 1993).

Two recent studies evaluating the impact of retrospective DUR offer more promising results. Using a pre-post, nonequivalent control group design, Zimmerman and colleagues (1994) found that a letter intervention for Wisconsin Medicaid patients resulted in a greater reduction of H2RA use in the intervention group than in the comparison group, as well as a decrease in drug expenditures which exceeded the cost of targeting and notifying physicians. The findings held for both ambulatory and institutionalized patients. The authors note that few other drugs represent such a large proportion of overall expenditures as the H2RAs. They conclude that it is unlikely that improving prescribing practices for other drugs would yield a cost-benefit ratio of the magnitude observed in the research. Another study found that letters sent to both physicians and pharmacists resulted in a greater percentage of patients discontinuing dipyridamole relative to controls and statistically significant differences in post-intervention dipyridamole expenditures relative to controls in both long-term care and ambulatory patient populations (Collins, et al. forthcoming 1996). This research reveals that when retrospective DUR is targeted to particular drugs, and adequate controls are present, letter interventions can make a difference. Further, it is noteworthy that in these two studies, interventions were targeted only to those physicians who violated the DUR criteria for a prolonged period and who had several patients for whom inappropriate prescribing decisions were made. Further, feedback was provided to physicians regarding several patients, not on a case-by-case basis. These features strengthened the intervention and could help account for the success of the program.

Few controlled studies have examined the direct effect of DUR on patients' outcomes, such as admission to the hospital. A notable exception is a controlled study of the Medicaid program in California, which revealed that retrospective review in several counties brought no changes in costs for health care or prescription drugs (Jay, Eynon, Javitz 1991). The negative results may have been due to the small percentage of prescriptions flagged by the computer that resulted in letters to physicians; to a lack of diagnostic information, so that the appropriateness of prescriptions could not be

determined; or to inability to identify the prescribing physicians for about one fourth of patients (Soumerai, Lipton 1995; Lipton, Bird 1991).

OBRA '90 authorized funding to evaluate counseling by pharmacists and prospective DUR. Demonstration projects in Iowa and Washington, funded by HCFA, will be completed by 1998. The Iowa project will test whether prospective DUR is cost effective and will examine outcomes, including the frequency with which potential drug-therapy problems are detected, the percentage of such problems that lead to an intervention by the pharmacist, and changes in hospital admissions for drug-induced illness. The Washington project will test whether reimbursing pharmacists for their counseling services increases the detection of problems, increases the number of interventions performed by pharmacists, and reduces the costs of drug therapy.

V. Study Findings

Since few conclusions about PBMs' impact on costs and quality can be drawn from the available literature, case studies of PBMs and interviews with their clients were conducted. In this section, the authors present a comprehensive description of the administrative and drug use control functions PBMs perform. When data are available, the impact of these functions on costs and quality of care is discussed and comparisons to Medicaid programs are presented. Next, the authors present the results of efforts to estimate cost savings in the PBM environment. Finally, additional comments from PBM clients and benefits consultants are presented.

Background Information on PBMs Interviewed

Interviews were conducted at seven PBMs (see Table V.1). The PBMs interviewed for this study have origins in claims processing and prescription card programs, retail pharmacy, mail order pharmacy, health insurance companies, and professional associations. The PBM firms were founded in years ranging from the late 1960s to the mid 1990s. Most of the PBMs interviewed are currently wholly-owned subsidiaries of publicly traded companies, including pharmaceutical manufacturers, managed care organizations, and retail pharmacy.

In Table V.1, PBMs are arrayed by relative size in terms of number of reported covered lives. The number of reported covered lives ranged from 1.5 million to over 25 million. In the Table, "large" PBMs reported 10 million or more covered lives; "medium" firms reported fewer than 10 million, but at least 5 million; and "small" firms reported fewer than 5 million, but at least 1 million. For purposes of comparability, these gradations in size are identical to those used in the Typology of PBMs presented earlier in this report. Another variable that can be used to determine PBM size is number of prescriptions managed on an annual basis. PBMs reported a range from 5 million prescriptions to well over 100 million prescriptions. The number of mail order prescriptions managed by the PBMs (via an internal mail order pharmacy or a subcontracted vendor) ranged from less than 1 percent to 25 percent of the total number of prescriptions managed.

PBMs were asked to describe the level of services provided to different types of clients, such as a "typical" client, a client using a "high-level" of services, and a client using a "low-level" of services. These terms meant different things to different PBMs, due to variation in their standard service packages, as well as in their primary client bases. Thus, the data reported (see Table V.1) are not standardized across PBMs; nonetheless, such data help describe the PBMs in terms of the variety and prevalence of different services and clients. For example, the prevalence of mail order utilization varies across different PBM firms, and some PBMs noted that large clients are more likely to use a "high level" of services. Greater detail about PBM services presented in the table (e.g., pharmacy network management, formulary services, drug utilization review (DUR), and disease

management) will be described in later sections of this report.

PBMs' management of Medicaid populations is also presented in Table V.1. Firms reported a range from 100,000 to about 2 million Medicaid covered lives. These Medicaid populations are enrollees in managed care organizations which have contracted with PBMs for management of the pharmacy benefit. Firms predicted an increase in the numbers of Medicaid covered lives as more states implement Medicaid managed care programs.

PBM Administrative Functions

1. Benefit Structure and Design

PBM responses to benefit structure/design parameters are summarized in Table V.2 below.

The PBMs reported that co-payments were the most common cost sharing approach used by clients, with some clients preferring co-insurance. One PBM respondent projected a trend towards co-insurance (typically 20 percent) and away from co-payments, given more expensive drugs being introduced and used in the market. Furthermore, a co-payment does not take inflation into account, whereas co-insurance does.

As an incentive for patients to use particular, preferred drugs or classes of drugs, a lower co-payment may be imposed when those drugs are dispensed. The PBM respondents reported such lower, differential co-payments usually were applied for generic drugs and sometimes were applied for formulary drugs. A consultant remarked "differential co-payments are the only thing that achieve an outcome. Floating fees for pharmacists based on dispensing performance had no impact on general utilization patterns."

Prescription size limits or suggested dispensing quantities were used by the PBMs we interviewed to foster efficient dispensing, especially for maintenance drugs. Nonprescription drug coverage varied among the PBMs interviewed, but generally only limited numbers or types of nonprescription drugs are covered. One PBM reported a unique plan that allowed beneficiaries to purchase up to $25 per month for nonprescription drugs.

Table V.1 PBM Background Information

PBM	Relative Size of	Level of Services Provided to Clients**	Primary Client Base	Medicaid Lives
•	large	60% of clients use national network, claims processing, DUR, mail order; 10% of clients (often large clients) use "high-level" services (e.g., enhanced reporting, prior authorization, formulary services); 30% use " services (e.g., "low-level network only)	MCOs	not reported
•	large	65% of covered lives use more than claims processing services; typical client uses claims processing, P-DUR, R-DUR, formulary management, integrated retail pharmacy network with mail service, account management and administrative support	managed indemnity, Fortune 500, BCBS	1 million
•	large	80% of covered lives are "managed" lives using claims processing, P-DUR, R-DUR, network administration, formulary development and management	corporations, insurers, BCBS	1.7 million
•	medium	all clients use clinical program services: formulary services, DUR, academic detailing, and reporting; the majority of clients use the claims processing system	BCBS plans, other insurers	over 100,000
•	small	40% of clients use a comprehensive package of services; large clients use more clinical management and reporting services than small clients	regionally-based companies and HMOs, local government	about 100,000
•	small	90% of clients use the typical package: formulary management, claims processing, network administration; less than 1% use mail order	BCBS, MCOs, Medicaid MCOs	1 million
•	small	50% of clients use high-level services (disease management, special DUR programs, special reporting); 20% of covered lives use mail order	employers 15% insurers 15% HMOs 15% Medicaid 15% unions 10% PPOs 10%	about 300,000

Large - PBM reports > 10 million covered lives

Medium - PBM reports 5 > 10 million covered lives

Small - PBM reports 1 > 5 million covered lives

** PBMs provided data at different levels of analysis. Some provided percentage of clients (plan sponsors) using a typical package of services, whereas others provided percentage of covered lives.

Table V.2
Summary of Characteristics of PBM Benefit Structure/Design

PBM	Co-payment	Deductible	Cap on #RXs	Cap on total $$/ yr or mo	Quantity limit	Minimum RX size	Patient incentives	OTC coverage
•	yes	in managed indemnity programs	no	yes, most often in Medicare risk arrangements	typically 34 day	none, based upon necessity	yes, mostly generic incentives, some formulary incentives	selective, more often with Medicaid coverage
•	75% co-pay, 25% co-insur.	rare	no	no	30-34 day, 90 (sometimes 60) for mail		yes, ~80% have generic incentives, a small % have formulary incentives	not often
•	yes, amount varies (commercial plans)	no						some covered
•	yes	yes	no	only 3-4 plans have annual caps; none on $$ per month	34 day or 100 for maintenance drugs	no, but recommend 30 day or 100 for maintenance drugs	yes, generic/brand, formulary/not (sometimes); coupons to steer to pharmacies	most plans exclude OTCs
•	"all" plans		no	yes, especially senior plans	34 day supply typically		yes, differential co-pay	sometimes, up to plan
•	yes						variable co-pay or coinsurance for generic/brand; pay difference for nonformulary drug	
•	nearly all	~15%	few	~5% have annual ~8% monthly cap	34 day or 90 day maintenance	no	yes, differential co-pays	yes, e.g. insulin

2. Mail Order Services

All PBMs that were interviewed included mail order prescriptions as an option. It is viewed as a standard component in the industry although varying levels of emphasis are placed on mail order prescriptions by different PBMs. History, ownership, and corporate philosophies and strategies influenced the emphasis PBMs placed on mail prescriptions as a component of their capabilities. For example, PBMs more closely aligned with pharmacy practitioners via ownership by a chain pharmacy or an affiliation with a state pharmacy association de-emphasized the mail service component of their PBM functions. One PBM executive remarked that "Part of our strategy is to integrate mail order with retail service so as to compete for total PBM business with large clients." Some firms almost seemed to regret having mail order, reacting, perhaps, to the pressure the market, especially clients with elderly beneficiaries, exerts on them to include mail as an option in their capabilities. Another PBM executive noted, "A PBM needs to provide mail service to be considered for some contracts."

Three of the PBMs interviewed recently acquired mail order prescription firms or were building their own facilities to incorporate mail order as an "in-house" capability. The reasons for these acquisitions included increased consumer/employer demands, ability to provide standardized pharmacist training for patient or physician interventions, presence of supervisory personnel and resultant pharmacist accountability, and effectiveness and efficiency in drug management efforts initiated in the mail service component." One PBM reported twice the success rate for switches initiated by mail service pharmacists compared to the retail network. They also noted a potential for efficiencies and reduced intrusion in contacting prescribing physicians by aggregating suspected drug therapy problems by physician and calling the physician only once daily. The following quote captures this notion expressed by two PBM respondents:

> *"Advantages of mail order: There are economies of scale which can be realized with mail order service, but their greatest capability is that interventions are easier and can show greater cost effectiveness. Why? The ability to control, and as we implement disease management, this becomes more and more important. With mail order, the pharmacist has a whole day to contact the physician or patient and arrange for a switch or conduct another type of intervention. At a retail pharmacy, they have 20 minutes at most."*

Another PBM commented, "The marketplace drives mail order in-house because it potentially cuts out a middle man." The PBM can control mail costs better and consequently be more competitive in its pricing to clients. Several PBMs raised the issue of friction between mail and retail pharmacies, and trying to reconcile this friction while offering both to clients.

Client Comments

Some clients we spoke with were not as enamored with mail order, noting, "There are no recent data showing its cost effectiveness." Another remarked:

> *"We're working with them to do what they publish they do. They're more 'show than go,' even though with one PBM, it's their agenda; they want to push their products. We haven't seen a lot of market share shift [to preferred products] with the mail order vendors. We haven't seen changes in prescribing practices either. However, a big portion of the future for pharmacy is in mail order."*

One client shared goals for retail and mail components of the PBMs with which they contracted:

> *"For 1996, on the retail side, we hope to earn more rebate money. On the mail side, we hope to improve performance standards, given the new increases in volume (in 1995 the PBM got 90,000 to 100,000 scripts per week, in 1996, 190,000). We want better customer service from their call unit."*

The same interviewee remarked:

> *"Implementing and paying for interventions is a different process on the mail versus retail side. We are paying one PBM to be a claims processor, network manager, and rebate negotiator, whereas we are paying another PBM as a mail service pharmacy. First off, we always are concerned that the cost of implementing the interventions is less than the drug cost savings achieved. Mail service pharmacists are trained to conduct interventions which are more commonly included in our charges, but these interventions are still an option offered to us, which we can choose to accept or turn down."*

Table V.3
Characteristics of PBM Mail Service

PBM	How Provide Service	"Size" of Mail	Incentives for Mail
•	Subcontracted, usually with 1 of 2 firms, but client can have own arrangement.	<5% of RXs	No
•	11 facilities in-house	40 million RXs, ~25% of RXs	Yes, 1 co-pay for 3 mo. supply. Not always same co-pay: $5 retail, $10 mail, but get 3 mo. supply
•	Subcontracted	<1% of RXs	N/A
•	Recently purchased in-house, also subcontracted	7 million covered lives, ~4% of RXs	Yes, 1 co-pay for 3 mo. supply
•	In-house (new) and subcontracted	have goal of 80-90% of covered lives	N/A
•	Subcontracted	5% of RXs nationally	Some plans cover more of cost for mail order
•	In-house facility (recent acquisition)	5% of RXs	Yes, 1 co-pay for 3 mo. supply; sometimes lower co-pays

3. Pharmacy Network

Parameters of interest related to PBMs and pharmacy networks (or "panels") in our interviews included number of participating pharmacies, their geographic dispersion, how and why pharmacies may be selected, how frequently panels change, and other aspects of pharmacy participation.

Network Description

The PBMs interviewed offer "national" networks of pharmacies with broad coverage and large numbers of participating pharmacies. They also reported having more restrictive panels available. The broad networks provide the greatest access, and typically have the highest reimbursement rates and fewer other drug use management control and performance parameters. Lower pharmacy reimbursement rates are negotiated for pharmacies participating in a more restrictive panel as a trade off for potential increased prescription volume in those pharmacies. Restricted panels offer the possibility of greater cost savings to sponsors because of the connection between pharmacy reimbursement rates and PBM charges to clients.

Table V.4 summarizes some of the findings for individual PBMs. Most of the PBMs described a broad panel and a restricted panel based on the number of participating pharmacies, and some characterized one or more intermediate, middle-ground panels. Strategies for restricting the panels focused on securing participation from one or a few chain pharmacies and adding other pharmacies to provide "sufficient" access coverage for the client. One PBM reported having about 200 networks targeted to individual client needs and requests. This statement probably is realistic because most clients primarily

need local or regional networks for most beneficiaries (employees), but potentially broad geographic coverage for exceptions such as covered retirees who have relocated or sales staff in different locales.

Most PBMs have wide geographic distribution of pharmacies by virtue of their national panels. They use computer zip code analysis in an attempt to ensure that participating pharmacies are located within a desired distance. For PBM plan enrollees in rural areas a 5 mile radius typically is used to gauge access and in urban areas a more restricted distance of 0.5 to 1 mile radius is used to assess access. This access parameter of distance to a participating pharmacy can be compromised with restricted, deeper discount networks.

Network Participation: Qualifications and Incentives

The PBMs reported that requirements to be a participating pharmacy typically were minimal. Pharmacies must be licensed, comply with reimbursement rules, maintain prescription records, charge required co-payments, etc. Some clients may have special requirements that limit pharmacies from participating such as a Spanish-speaking pharmacist available. Generally, PBMs do not turn providers away, especially for the broadest pharmacy networks; they like to have broad coverage and access to offer clients.

Qualifying credentials for participation also were basic, for example, no board actions against the pharmacy, a specified level of liability insurance protection, etc. There is a tendency for larger PBMs to engage in profiling and qualifying or credentialing pharmacies for preferred provider status based on PBM performance parameters such as formulary compliance, generic dispensing rates, usual and customary price reporting, and response to prospective DUR alerts. Other PBMs are planning or moving toward this credentialing process as they gain capabilities to monitor and tract pharmacy performance. Some "special" network members are expected to undergo continuing education training to qualify for preferred provider status. The qualifying process intends to capture quality parameters of providers (e.g., process characteristics such as training and expertise of pharmacists and clinical systems) or "operations" characteristics (e.g., structural characteristics such as FAX machines, hours of operations, etc.).

A PBM consultant stated that PBMs are credentialing pharmacies for certain structural characteristics, such as diabetes management pharmacist certification. However, they are not focusing on performance issues, such as which pharmacies are doing effective patient counseling. They want to start using performance or quality of care parameters, but this is not happening yet.

The surveyed PBMs we interviewed did not have explicit participation incentives. However, by default, participating pharmacies retain existing patient populations and can gain patients if other pharmacies in their market area do not participate as providers in the PBM panel. Some PBMs have special programs that include payment differentials such as

performance based dispensing fees, cognitive services payment, generic incentive fees, and added fees for delivery. Also, different dispensing fees may be negotiated with some providers such as rural or inner city pharmacies to ensure access for client patients.

Network Restrictions

Restrictive networks of pharmacies can result by deliberate PBM selection efforts or from a "self selection" process among pharmacies. The PBMs reported they use selective contracting to develop restricted pharmacy networks. These selective contracts typically offer reduced reimbursement to participating pharmacies and thus lower cost to clients. The selection criteria also may be performance-based or linked to special capabilities or characteristics of the providers in the network, such as meeting targeted generic dispensing or formulary compliance rates, or 24-hour store availability. At present, performance aspects that PBMs monitor are very basic, thus the selection criteria also tend to be limited. Barriers to selective contracting, as perceived by the PBMs, include opposition from organized pharmacy, any willing provider legislation, and employer reluctance to limit access to pharmacies for employees and subsequent potential employee dissatisfaction.

Pharmacy panel restriction by self selection occurs when not all pharmacies agree to the reimbursement terms or performance parameters and thus are excluded from some networks. Any willing provider laws stipulate that all pharmacies agreeing to accept reimbursement terms and satisfy performance requirements can participate if they choose. PBM clients effectively "restrict" networks by choosing payment levels and performance aspects for their desired providers.

Attempts to restrict networks were described aptly as a "catch 22" for pharmacies and PBMs by a PBM consultant. PBMs say they will contract with a small pharmacy network to reduce reimbursements in trade for increased volume in the restricted panel pharmacies. But, with "any willing provider" laws, additional pharmacies agree to the reduced payment terms, diluting the market share the PBM can deliver to the originally intended restricted network pharmacies. Consequently, the original pharmacies may withdraw from the network because they would be locked into deep discounts without any corresponding volume advantage.

Changes in the Pharmacy Network

Usually the size and composition of PBM networks are quite consistent over time, reflecting only changes in local markets from closures and openings, with minimal changes initiated by the PBMs for performance or qualifications reasons. The pharmacy contracts can vary, but typically 1 to 2 year contract terms occur (unless clients prefer different periods). Performance standards and fraud criteria are in place to remove pharmacies from panels. One firm reported 4 to 5 percent of network pharmacies annually receive

targeted inspection by PBM consultants after review of pharmacy activities on performance standards. This firm noted about 15 contracts terminated each quarter due to fraud or performance problems. It also is possible to have changes resulting from pharmacy participation decisions as occurred in Maryland with the State employees contract, but such situations have been uncommon to date (Slezak Jan 1996).

Table V.4
Characteristics of PBM Pharmacy Networks

PBM	Broadest	Intermediate	Restricted	Notes
•	"everyone" ~47K pharmacies	Select chain(s) and preferred partners	1 chain only (more than 2,000 drug stores) - typically for "local client" contracts	
•	"everyone" ~48K pharmacies		2 chains (w/ "sufficient access") and open to any others meeting reimbursement. terms	
•	54K+ pharmacies	44K+ or 53K+ pharmacies	21K+ pharmacies, 38% of pharmacies nationwide, panel is 70% chain pharmacies	
•	~47K pharmacies	~42K pharmacies in deeper discount panel	1 or 2 chains for deep discounting, then open to any other meeting reimbursement terms	
•	53K+ pharmacies, all chains and 98% of independents	45K+ or 52K+	40K+ pharmacies, chain based network	3 additional pre-contracted networks and customized networks
•	98% of state pharmacies	Preferred network meeting criteria/credentials		Planning for selective group that will provide specialized high level disease management services, etc.
•	40K+ pharmacies			Selective contracting with credentialing

4. PBM Charges To Clients/Financial Arrangements

The PBMs reported using a variety of mechanisms for charging clients for their services. They often remarked that the charging approach depends on the desires of clients and that they can do whatever is preferred. However, there also were some indications that some charging mechanisms, particularly capitation, were not as desirable to the PBMs.

A common charging method is a per prescription claim administrative fee. This reflects the relation between one primary activity of PBMs, claims processing, plus associated activities that occur on a per prescription basis such as prospective DUR, and resource use. Additional fees either on a per claim, per covered life, per member per month (PMPM), or lump sum per month are assessed for clinical programs such as formulary management, retrospective DUR, disease management and other activities/functions that may not be claim volume dependent. Rebates associated with drugs used by client beneficiaries also factor into financial arrangements with clients in the form of a shared percentage of rebates earned.

One respondent observed that a fixed PMPM administrative fee for clinical management can help avoid an incentive for increased utilization on a per claim charge. Further, he stated that "The 'old' PBMs did not charge for clinical management; that's why the client did not get any." Currently, by charging for clinical management, clients may be more likely to receive clinical services. Several PBMs emphasized the potential for savings beyond drug budgets when drug therapy is managed appropriately; there is growing acceptance of this broader view.

Risk arrangements, particularly capitation, are not very common as charging methods, but are gaining interest and momentum among clients. Some respondents reported that other PBMs attempting at risk, capitation contracts have experienced losses and there is a mixed response to the potential of capitation. An exception to the limited enthusiasm for capitation was one PBM with much of their business in capitated contracts. That executive believed capitation had the most potential for overall reduced cost and control, particularly for a Medicaid population.

Shared risk arrangements (e.g., for a PMPM risk corridor with savings/loss sharing) are being attempted in cases where PBMs have a good relationship and/or willing contractual partner. More commonly, a PBM might respond to client requests for "guaranteed savings;" thus, the PBM will go "at risk" for achieving the promised savings levels. A challenge arises in how these savings may be measured, e.g., what is the comparison baseline cost and how are savings determined? As clients become more sophisticated and as fewer "unmanaged" client populations exist, these "guaranteed savings" schemes have less potential for sizable saving levels and become less popular.

The PBMs also reported that as clients become more sophisticated (or use a benefit consultant), they look for performance guarantees. To one PBM, the focus on

guarantees almost has taken on the character of a game, noting that "If something can be measured and quantified within the PBM activities and thus the contract, soon thereafter [the client will require that] there will be a performance guarantee based on it." An example offered was the amount of time it may take for a mail service pharmacist to answer the telephone to respond to a patient question; in what percent of calls is the phone answered in 4 rings or less? Clearly, there is potential for some performance aspects to be more important than others. Some more easily measured variables (e.g., % < four rings) may be less significant than other more complex parameters (e.g., % of serious drug-drug interactions averted).

PBM Drug Use Control Functions

1. Formulary and Formulary-Related Activities

Formularies

This section includes a description of different types of formularies used in the PBMs surveyed, the processes by which formularies are developed and compliance is encouraged, and information available on the value of formularies. Formularies were used in all PBMs under study as a mechanism to control costs and, to a lesser extent, improve quality. Types of formularies vary based on the number of drugs covered within a certain therapeutic category, the costs incurred by the patient to obtain the drug, and the presence of interventions to direct drug utilization to formulary products. As discussed in the trade press and peer-reviewed literature, several types of PBM formularies emerged from the PBM case studies, including open, closed, and managed formularies[12] (see Table V.5).

Most PBM covered lives -- ranging from 80 to 100 percent -- receive some type of formulary management services, although one PBM reported that only 50 percent received formulary services. Smaller PBMs may contract out formulary services; one PBM studied contracts with a Blue Cross and Blue Shield organization to utilize its formulary program. However, many PBMs have their own independent Pharmacy and Therapeutic (P&T) Committees which develop and update the formulary at quarterly intervals and provide input into other clinical areas (i.e., the development of disease management programs).

Formulary development and maintenance

Formularies are developed by physicians and pharmacists on P&T committees who weigh clinical and cost issues to rate prescription drugs in the same therapeutic class and consider new FDA-approved drugs, newly approved indications, and generic drugs for inclusion on the formulary. All PBMs except one maintained their own P&T committees.

[12] For definitions, see literature review section on Formulary and Formulary-related Activities.

Some PBMs noted that the P&T committee considers drug cost in making formulary decisions, but one PBM insisted that the P&T only considers clinical issues; PBM administrators factor drug cost into final formulary decisions about products which the P&T has indicated "may" (as opposed to "must") be included on the formulary. Another PBM stated that it did not bring rebate arrangements into formulary development, whereas others made such considerations explicit. After the P&T renders its formulary decisions, PBMs then engage in "intense discussion" with manufacturers to obtain competitive pricing and rebates agreements, which hinge upon the PBM's clinical management programs to shift market share of a manufacturer's product. Some manufacturers now "guarantee results" or are negotiating with PBMs or MCOs to engage in risk sharing as a means of gaining product acceptance on formularies.

Formularies include both brand and generic products. A few reports from interviewees (and noted in the trade press) indicate that PBMs may favor a brand over a generic in their formularies due to manufacturer rebates which make the brand price-competitive with the generic (Epstein 1995). One PBM with a large number of Medicaid covered lives emphasizes the development of generic formularies, as opposed to brand name formularies driven by rebates. This PBM reported generic dispensing rates of 65 percent. PBMs reported giving limited consideration for formulary inclusion to "me too" brand products which are chemically and therapeutically similar to products already on the market.

In general, PBMs and their P&T committees are responsible for designing and implementing the formulary, although the client may be able to modify the formulary if desired. PBMs reported that customer modifications are usually minor. Larger, more sophisticated clients who may have internal pharmacy staff are more likely to require modifications to the PBM-designed formulary; the client's in-house pharmacist may meet with the PBM P&T committee on a regular basis. Some PBM customers, such as MCOs and insurers, may have their own P&T committees; in fact, two PBMs noted that "most" of their clients used the PBM P&T committee as a consultant to their own committees. In this case, the PBM may serve in a collaborative role to guide formulary decisions for these clients. Some Medicaid MCOs are required to use their state's Medicaid formulary which the PBM implements for its Medicaid members. Other clients, such as Blue Cross and Blue Shield plans, may also require the PBM to implement their own formulary.

PBMs reported that smaller-sized clients and employers tend to accept the PBM as "the expert" on formulary decisions and approve the use of the PBM formulary without modification. The prevalence of PBM-designed formularies versus client-tailored formularies also differed across the PBMs studied. Some PBMs reported that "most" clients used the former, while other PBMs reported that "most" clients used the latter (see Table V.6), depending on their client base.

Formulary type

The majority of PBM covered lives are on an open formulary, but interviewees mentioned a growing trend toward managed and closed formularies and an emphasis on generic drugs. This trend is particularly evident among PBMs' managed care clients. Indemnity insurance and large employer clients, particularly unions, typically use open formularies. Their members are accustomed to generous health benefits and have greater influence in resisting benefit design changes by the plan sponsor. However, some PBMs reported increasing interest in managed formularies among managed indemnity clients. They attributed this interest to the belief that significant cost reduction could not occur without the implementation of a managed or closed formulary. PBMs also explained that rebate contracts with manufacturers now require them to document quantifiable shifts in market share in order to obtain rebate dollars, a process difficult to achieve with an open formulary.

According to a recently-released study of 150 corporations, interest in implementing formularies for employees is rising.[13] Several PBMs commented on increased interest in and prevalence of managed formularies:

> *"Movement is toward managing the patient and away from managing the unit cost of drugs as a total management principle. So the open formulary is here to stay, but in the old paradigm, an open formulary was an unmanaged formulary -- all drugs were included and there wasn't a lot of intervention. Our [open] formulary involves a lot of active management and intervention with the prescribers."*

> *"There will be a greater emphasis on balancing costs with clients' and patients' desire for open access. Formularies will be considered plan design features, rather than primarily cost reduction measures."*

PBMs and their clients are encouraging providers to prescribe and dispense formulary products with a variety of mechanisms from education to financial incentives, but aggressive formulary enforcement is relatively rare the PBM world. The number of PBM covered lives on a closed or managed formulary remains relatively low, generally between 10 to 25 percent of total covered lives in PBMs studied (although one PBM estimated 40 to 50 percent of covered lives). Many plan sponsors have not begun denying coverage for non-formulary drugs; patients may pay more for these drugs and prior authorization for "medical necessity" may be necessary.

An interviewee at a PBM linked the type of formulary implemented to the level of PBM accountability desired by the client:

---

[13] Data from the 1995 National Survey on Advanced Pharmacy Benefits by William M. Mercer; as reported in *Managed Pharmaceutical Report* April 1996. p 10.

"If a client wants a savings guarantee or wants us to assume risk, we would require a managed formulary. The client will have to agree to take the formulary online at the pharmacy network, and physician offices must be made aware of the formulary. We would require academic detailing to allow us access to talk to providers. For a fully capitated contract, we would require a closed formulary."

It appears that much of the variation in the types of formularies and the way they are implemented can be attributed to differing client needs and expectations -- which have intensified with the growing sophistication of PBM clients. Rather than make generalizations about the type of formulary (e.g., open, closed) used by a certain type of client, one PBM interviewee noted:

"More importantly, it is the way that we implement and manage the formulary that differs from client to client."

Physician compliance with formulary

As noted earlier, clients using or moving toward more managed formularies tend to be managed care organizations (MCOs). PBMs stated that MCOs had greater ability to change benefit design and influence physicians' prescribing practices and, therefore, were more able to implement a managed or closed formulary. Changing physicians' prescribing practices is the key to success for PBMs' formulary management activities. Efforts to increase physician compliance to the formulary include:

- copies of the formulary and written educational materials mailed to physicians
- calls to physicians from pharmacists prompted by on-line, point-of-sale reminders that the prescribed drug is off-formulary or a generic is available (one PBM has two "call centers," or non-dispensing pharmacies, from which formulary compliance interventions are initiated)
- PBM-employed pharmacists are assigned to visit physicians serving a particular plan sponsor or those located in a specific geographic region
- copies of the formulary, condensed versions of the formulary, and/or lists of preferred products are sent to members, who are encouraged to present the formulary to their physicians
- personal formulary compliance reports sent to individual physicians and/or plan sponsors (MCOs)[14]

[14] PBMs differ with respect to policies about reporting to plan sponsors the physicians who are "prescribing outliers." See DUR section.

- letters about a particular patient's drug therapy with recommendations for changes to formulary and/or generic products which can be inserted in the patient's chart for future reference

- prescribing guidelines or protocols approved by the P&T committee disseminated to physicians

- development of on-line, real-time computer system communications to the prescribing physician from the PBM indicating if the intended prescription is listed on the patient's formulary and which agents are included on the patient's formulary

PBMs use combinations of one or more of the above tools depending upon client requests and PBM capabilities. Some PBMs, especially smaller companies, rely on their clients to provide formulary education and incentives for formulary compliance, if desired, to providers and patients. One PBM noted that mailing formularies to physicians does not influence prescribing practices:

> *"Doctors don't use the formulary alone; a more aggressive intervention is going to be necessary to influence prescribing behavior, such as calls from pharmacists. We've had great success with programs that notify physicians of patients taking non-formulary medications and offer formulary alternatives."*

Prior authorization (PA) involves a requirement for mandatory advance approval for the use of certain medications (Smalley, et al. 1995). Placing drugs on the prior authorization list is a mechanism plan sponsors and PBMs use to protect patients from potentially dangerous drugs and to reduce unnecessary or excessive drug costs; prior authorization programs may help enforce the formulary by restricting access to nonformulary drugs. Prior authorization functions may be performed by the PBM or, alternatively, by its MCO client. (Some PBMs do not perform prior authorization functions, but they will provide their clients with drug therapy guidelines.) Certain drugs, quantities or doses of drugs, a particular patient's access to drug(s), or plan members' access to specific drug(s) are coded in the on-line, point-of-service system to require approval prior to claim adjudication. Depending on the PBM and the client in question, either the PBM or the client may be responsible for handling appeals from patients for coverage of a nonformulary drug when the prior authorization has been denied.

Prior authorization programs' success is difficult to gauge. Some interviewees mentioned that 80 to 85 percent of prior authorization requests are approved and that the percentage is increasing as physicians gain experience with the prior authorization process and documentation requirements. Other PBMs declined to answer questions about the percentage of approvals. The approval rate at PBMs is lower than at Medicaid programs,

which are reported to approve 95 percent or higher of the requests for drugs on prior authorization. These high rates of approval raise the issue of cost-effectiveness: PBMs, their clients, and Medicaid programs must assess whether the costs of implementing a prior authorization program outweigh the drug cost savings achieved. A PBM interviewee commented that one role of a PBM is to educate clients and help them evaluate cost-effectiveness issues, such as those related to prior authorization programs. For example, with some very expensive drugs, prior authorization programs result in net savings for the client with only a few denials.

An interviewee at a Medicaid MCO reported that since their drug plan has been contracted to a PBM, adjudication of prior authorization requests is handled in about one day. Previously, the paperwork sometimes was not processed for several weeks. The MCO reported that 80 percent of prior authorization request are approved; a lower proportion than under the state program. The interviewee believed that the lower approval rate with the PBM-administered PA program was due to greater stringency and a more efficient formulary, for which drugs on the prior authorization list had been carefully reviewed before their exclusion.

In addition to the educational approach used to encourage physicians' formulary compliance, some MCOs have capitated physicians for drug costs, or instituted "withholds" based on formulary compliance. Many more MCO physicians are capitated for overall health care costs. According to PBMs, the assumption of risk for pharmacy utilization is a powerful incentive enhancing physicians' willingness to comply with formularies. PBMs predict greater use of financial incentives to encourage physicians' formulary compliance in the future.

Pharmacist compliance with formulary

To encourage formulary compliance by pharmacists, several PBMs stated that they had instituted financial incentives, such as "floating" dispensing fees based on formulary and/or generic dispensing performance for specific pharmacy networks. In effect, pharmacists are accepting accountability for their services, in that reimbursement is based on their level of performance. Another incentive focuses on costs -- the PBM calculates average PMPM cost for a defined region of pharmacies. Pharmacy providers in that region are rewarded with higher fees if the PMPM cost is lower than the budgeted amount, and fees are decreased if the region exceeds the budget This trend may grow as PBMs increasingly agree to risk-sharing or capitation arrangements with clients, because they may chose to transfer some risk to the pharmacists. However, one interviewee questioned whether floating dispensing fees were effective in stimulating changes in dispensing behavior. Empirical evidence that these type of incentives have an impact on dispensing practices was not available. Some interviewees suggested that pharmacists' willingness to respond to such incentives is mitigated by other requirements and incentives created by PBMs, such as high volume dispensing of product and time-intensive documentation of drug interchanges.

Another approach to encouraging pharmacists' compliance with formularies is performance-based pharmacy contracting. To build preferred pharmacy networks, PBMs may contract with pharmacies that meet standards of formulary compliance, generic dispensing, or other factors, such as effective package size use and value of usual and customary pricing. Pharmacies may be dropped from the network if they fail to achieve these minimum standards (see further discussion in Pharmacy Panel section of the final report). Performance-based contracting may function as an effective incentive for compliance with formularies, but no empirical data are available to validate this hypothesis and many such programs are in the beginning stages. One pharmacy expert noted that the level of enforcement of formulary dispensing standards may be limited in rural regions where PBMs must include pharmacies in their networks to ensure access.

Patient compliance with formulary

At the patient level, formulary compliance is encouraged primarily through educational materials promoting preferred drug lists and financial incentives, such as differential co-payments for formulary versus non-formulary drugs and for brand versus generic drugs. PBMs noted that creating patient demand for formulary, preferred, or generic drugs would lead to increased formulary compliance by prescribing physicians. However, PBMs noted that using financial incentives must be weighed against the risk that higher co-payments may put an MCO at a competitive disadvantage.

Several PBM interviewees noted that OBRA restrictions on the use of co-payments for Medicaid recipients prevented their use as tools to drive formulary compliance. However, Medicaid experts have concerns that co-payments may negatively influence Medicaid recipients' utilization of necessary health services, including prescription drugs.

The value of formularies

Very little information is available about how PBMs measure success of formulary management interventions. We know:
(1) PBMs must report market share data to manufacturers to claim rebates.
(2) One claimed that it reports on formulary compliance to clients and manufacturers.

Although one PBM reported that a closed formulary could yield a 4 - 8 percent savings for a client, in general, PBMs were not forthcoming about the level of cost savings achieved through the use of formularies. Some PBMs considered this type of information proprietary, while others felt that aggregates of multiple clients' cost savings were not statistically meaningful.

One interviewee explained that PBMs have reduced drug costs for their clients by

fostering competition within drug therapeutic classes, particularly with regard to "me too" drugs.

Some clients indicated that they believed formulary management slowed growth of per member per month costs. One interviewee asserted:

> *"In order to obtain this slow-down in PMPM increases, we added a few more drugs to Prior Authorization, stepped up physician education about the formulary, improved the formulary, tracked high cost drugs, developed patient-friendly guidelines about lower-cost prescription drugs, and developed clinical guidelines."*

Several PBM clients commented that Medicaid programs would obtain better value in the long-term by increasingly managing their formularies, rather than including a broad spectrum of drugs for which rebates are obtained. Interviewees felt that Medicaid formularies' broad scope prohibits their use as a clinical tool providing guidance to physicians. Moreover, PBMs contracting with Medicaid MCOs often have little leverage with formulary management, because the MCO formularies are required to be identical to the state formulary. This lack of flexibility was perceived by some interviewees as a disadvantage for managed care plans with Medicaid clients.

Table V.5
Type of Formulary -- Open, Managed, or Closed -- Offered by PBMs

PBM	Open, Managed, or Closed Formulary
•	About 20 percent of clients (representing almost half of total covered lives) use managed or closed formularies, especially large MCOs and/or those with Medicaid enrollees.
•	Most formularies are closed.
•	Most formularies are open, but the number of clients using or interested in managed and closed formularies is growing.
•	Most (75 percent) clients use open formularies, but interest in managed formularies is growing on the part of managed indemnity clients.
•	About 90 percent of covered lives use an open formulary, but providers are encouraged to use formulary drugs. Only 10 percent use a closed formulary although there is decreasing resistance to the idea.
•	About 85 percent of covered lives use an open formulary; 5 percent use a closed formulary and 10 percent use a managed formulary. Prevalence of managed formularies is growing.
•	The PBM formulary is open, but the PBM is developing a managed formulary.

Table V.6
Type of Formulary -- PBM-Designed or Customized by Client

PBM	PBM-Designed or Customized Formulary
•	Most clients use a PBM-designed formulary; some (particularly HMOs) customize the formulary.
•	The PBM contracts externally for a formulary program. The formulary is accepted without customization by most PBM clients, with the exception of a Medicaid MCO client which has its own formulary.
•	75 percent of clients use PBM-designed formulary, but the number of formularies customized by clients (particularly Blues and HMOs) is growing.
•	Most formularies are customized by the client and implemented and maintained by the PBM.
•	Most clients use a PBM-designed formulary -- many clients are small employers who tend to accept the PBM's recommendations.
•	Most clients use a PBM-designed formulary; only about 10 percent customize the formulary.
•	Most formularies are customized by the client and implemented and maintained by the PBM.

Interchange Programs

Generic interchange (or generic substitution) is a switch from a brand-name drug to a chemically-equivalent, generic alternative. Unless the physician has noted "Dispense as Written" on the prescription, the patient can authorize or accept the change to a generic drug without prescriber approval. Under some states' generic substitution laws, the pharmacist will automatically switch the prescription from brand to generic unless the physician has noted "Dispense as Written."

Therapeutic interchange (or therapeutic substitution) occurs when a pharmacist contacts a physician for authorization for a switch in prescription, such as from a nonformulary to formulary drug, when the new drug is chemically different from the originally prescribed drug but has a comparable therapeutic effect. A primary goal is to foster more appropriate drug therapy. Some PBMs also contact the patient to increase the success of therapeutic interchange.

PBMs and generic substitution

Generic substitution is more common and less controversial than therapeutic interchange. All PBMs interviewed for this study offer their clients generic interchange programs or incentives for patients or pharmacists to use generics. One PBM felt that rates of generic dispensing almost have been maximized, with further increases of 5 to 10 percent possible, but difficult to achieve. Two other PBMs reported that the target generic dispensing rate is in the 70 to 90 percent range within a particular drug class; 100 percent is neither possible nor desirable because "stabilized patients should stay on their current drug," according to one PBM interviewee.

PBMs outlined two approaches to increasing generic substitution: plan design pricing components, such as maximum allowable cost (MAC) programs, or interventions directed at pharmacists, such as "floating" dispensing fees based on their generic dispensing rates as compared to peer norms in the region (see formulary section of final report). Another PBM reported that it sends letters to pharmacists reminding them about contractual obligations to meet certain generic dispensing standards, with penalties that include possible removal from the network.

PBMs and therapeutic interchange

Therapeutic interchange programs are often integral components of PBMs' efforts to increase formulary compliance and shift market share to preferred or rebated products. About half the PBMs studied explicitly offer therapeutic interchange programs, including pharmacist reimbursement, although several of these programs are relatively new (see Table V.7). PBM clients may be required to pay extra for interchange programs conducted in the retail network.

The remaining PBMs studied integrate therapeutic interchange concepts in other clinical management activities. These PBMs influence the utilization of formulary drugs via closed formularies, prior authorization programs, and prospective-DUR messages to pharmacists. PBMs without therapeutic interchange programs reported that pharmacists are encouraged to contact physicians about switches to formulary products, but are not reimbursed for their "interchange" interventions (see section on cognitive services).

A central feature of therapeutic interchange programs is communication with prescribing physicians for approval of the switch. Typically, this communication occurs via a telephone call from the pharmacist to the physician's office. PBMs noted that retail pharmacists may have difficulty handling a large number of these calls while simultaneously processing prescriptions, dispensing drugs to patients while they wait, and managing other pharmacy responsibilities. Some interviewees believed that a primary advantage of mail order pharmacies is their ability to conduct interchange interventions more successfully than retail pharmacists; they asserted that mail service pharmacists face fewer time pressures in contacting the prescribing physician, undergo training in communications skills, and have been educated about targeted disease states and drug therapeutic classes (see section of final report on mail order). One interviewee at a PBM client reported:

> *"We don't have therapeutic interchange on retail side, but we're working on developing this function with our PBM. We think interchange programs are effective; manufacturers do too. Yet, there are definite advantages to interchange interventions in the mail sector (e.g., more time for telephone calls to physicians), and we don't pay separately for interchange activities in mail service pharmacies."*

Because the majority of all prescriptions are filled in a retail setting, the cost savings of a therapeutic interchange program cannot be fully realized for a health plan unless therapeutic interchanges are successfully conducted in both the retail and mail order settings. As a result, some PBMs reported that they are attempting to create new approaches to circumvent the problems with retail-pharmacy-based interchange programs. One PBM recently implemented a new program which enables pharmacists to obtain online permission for drug switches with physicians who are linked to the system. PBM interviewees believed that online systems linking physicians to pharmacies, while in the early stages of development, may result in greater efficiency and better formulary

compliance for pharmacists, patients, and physicians. PBMs may also contact the patient for permission to call the physician about the therapeutic interchange.

While many PBMs rely on retail pharmacists to participate in interchange programs by directly contacting physicians, some evidence indicates that PBM strategies (on the retail side) are coalescing around physician calling programs. One PBM has used this approach for several years, and two major competitors are currently planning and implementing physician calling programs. Increasingly, PBMs believe that physician calling is an effective approach to influencing prescribing behavior:

> *"If you call a particular physician a certain number of times, he's going to change his prescribing behavior. After calling a physician four or five times, the educational strategy ("physician management" strategy) works."*

However, no information about how the PBM arrived at this conclusion was presented. Another interviewee asserted that physician education would affect prescribing practices not only for PBM patients, but non-PBM patients (or other PBMs' patients). However, different PBMs use different formularies and/or label different drugs as "preferred." Thus, physicians may be receiving mixed messages from various PBMs' therapeutic interchange programs.

Some PBMs' physician calling programs involve centralized call center operations. The "call center pharmacy" (non-dispensing) is staffed by PBM-employed pharmacy technicians and supervisory pharmacists to whom retail pharmacists may defer certain interventions. For example, the call centers may be used when retail pharmacists do not have the time or do not wish to call physicians for drug switch approvals. One PBM asserted that successful interchange programs must be built on standardized physician calling programs with dedicated staff. The PBM stated that success is unlikely when interchange programs rely on efforts of pharmacists at 50,000 different pharmacies nationwide who lack the time, opportunity, and training to conduct the interventions. One PBM interviewee commented:

> *"The easier you can make it for the doctor, the greater the likelihood that [the interchange program] will work. You're always analyzing what you can do to be less intrusive, less demanding of their time. Is there a way for the call center pharmacy to aggregate the calls to a physician and place them all at one time during the day?"*

Critics of physician calling programs feel that physicians are harassed by these calls and have too little time to handle the increasing volume of calls from PBMs or pharmacists. PBM clients were divided on the issue: some felt that physician calling was effective and appropriate, while others believed that written communications were more acceptable to physicians. Moreover, the above PBM's idea of aggregating telephone calls

to physicians at call centers was met with skepticism by some experts who doubted its practicality. One PBM which does not operate a call center asserted that retail pharmacists are acquainted with local physicians and therefore, are more likely to obtain interchange approvals than call centers (or mail order pharmacists). Another PBM utilizes academic detailing as an alternative to calling physicians and reports the program is "successful."

One PBM described its interchange program's comprehensive development and implementation process. The new drugs targeted for the interchange program undergo a clinical review by the P&T committee to determine therapeutic interchangeability and the conditions under which an interchange would be appropriate. The PBM conducts an economic review to assess cost savings. In the next step, the PBM develops "call guidelines" that will govern pharmacist-physician communication and written materials directed to the physicians. These materials are reviewed by the P&T committee. Focused training is conducted for pharmacists on communications skills, specific product information, and knowledge about the disease state in question. These pharmacists, located at centralized call center pharmacies and mail order pharmacies, call physicians who have been identified by weekly claims analyses (retail) or at point-of-dispensing (mail). If the physician agrees to a switch, the call center mails a letter to the patient to bring to the pharmacy at the time of the next refill, at which point the retail pharmacist contacts the physician for final approval. The PBM asserts that its "hit rate" (approved switches/total contacts for switch approval) is 25 percent in the retail sector and 50 percent in the mail sector. These data correspond to the claims of another PBM, whose new program showed in test markets that about 50 percent of patients and 60 percent of physicians agreed to convert to a preferred drug, accounting for a switch in about 30 percent of total prescriptions written under the program (*Managed Pharmaceutical Report* June 1996:5).

The drugs targeted by interchange programs are selected carefully; these interventions are time- and labor-intensive, as well as costly, and manufacturer rebate dollars are at stake. To be considered successful, the drug cost savings achieved through the interchange program must exceed the costs of program implementation. The PBM may have signed a savings guarantee with its client and will have to cover any net losses incurred by its interchange program. An interchange program's "hit rates" are crucial data because the PBM's success in increasing utilization of preferred products is critical in terms of rebate contracts. One interviewee stated:

> *"We're doing these [interchange programs] to support manufacturer contracts to demonstrate our ability to move market share in therapeutic classes where it is critical to do so to sustain rebates."*

Interchange programs and physicians

Several PBMs described their efforts to increase physicians' formulary prescribing;

these interchange activities may take place within the rubric of retrospective-DUR programs. In general, these efforts involve written communications, such as educational materials and computer-generated personalized reports. The PBM sends the physician a letter listing targeted high-cost medications which the physician has prescribed during the past quarter and recommends prescribing lower-cost alternatives. Letters may list patients who are taking nonformulary medications for whom alternative formulary products may be equally or more appropriate. One PBM formats a letter for each individual patient, so it can be inserted into the patient's file, acting as a reminder about the preferred drug when the patient visits the physician.

One PBM cautioned that to achieve cost savings, interchange programs are best directed at physicians who are high-volume prescribers in the drug category targeted. Changes in low-volume prescribers' behavior will not be significant in offsetting the costs of the intervention.

Financial incentives

Most PBMs did not report offering incentives to pharmacists, physicians, or patients for drug interchanges, with several exceptions. Pharmacists may be reimbursed for interchange interventions (see section on cognitive services reimbursement); one PBM stated that pharmacists will be paid for the time they spend calling physicians for permission for a drug switch. Other PBMs state that they do not reimburse pharmacists for drug interchanges. In many PBM plans, patients save money (e.g., reduced co-payments) when formulary and generic drugs are dispensed.

Several interviewees at both PBMs and their clients asserted that placing prescribers at risk would increase their acceptance of interchanges to formulary and generic products. In some cases, MCOs place physicians at financial risk for their prescribing patterns (e.g., financial withholds from their total capitated rate dependent on formulary or generic prescribing performance). If these withholds do not take medical expenditures into account, physicians could be penalized for appropriate drug utilization which, for example, prevents hospitalizations. One PBM expressed the hope for more sophisticated measures in the future, such as clinical decision rules and consensus guidelines established by professional medical associations, to prevent risk-based agreements from negatively affecting quality of care.

The results of interchange programs

The primary goal of therapeutic interchange programs is to reduce drug costs and maintain rebates. It is difficult to assess if these programs have an impact (either positive or negative) on patient health outcomes and overall medical costs. Data on cost savings achieved through interchange programs in terms of impact on total health care expenditures are usually unavailable.

Table V.7
Characteristics of therapeutic interchange programs

PBM	Therapeutic interchange activities
•	Utilization is driven by formulary implementation.
•	No therapeutic interchange programs; utilization is driven via formulary implementation and prior authorization.
•	New program offers interchange programs integrated into both retail and mail settings.
•	Contracts with pharmacies require minimum levels of formulary compliance. Noncompliant pharmacies can be dropped from the network.
•	Utilization of formulary drugs is driven via closed formularies. Pharmacists' phone calls to physicians are promoted.
•	Interchange activities are conducted via mail order pharmacies and pharmacy call centers on retail side.
•	No therapeutic interchange programs; utilization of formulary drugs is driven via P-DUR messages.

Cognitive Services Programs

In the context of the PBM environment, cognitive services often are viewed under the umbrella of formulary management, as mechanisms to control drug use by directing providers and patients to the use of "preferred" drug products. In contrast, pharmacists traditionally view cognitive services as the application of their professional expertise and judgment in improving patient drug therapies and enhancing the quality and outcomes of physicians' prescribing practices. This disparity in PBM and pharmacist perspectives may explain some of the low rates of pharmacist participation associated with cognitive services programs implemented by PBMs.

PBMs typically used the term "cognitive services" to refer to pharmacists' actions in responding to online DUR messages at point-of-sale, such as contacting the physician about switching a patient's prescription, successfully obtaining approval for the switch, reversing a prescription, or modifying medication dosage, as well as counseling patients on their drug therapy or their formulary. Within the context of a disease management program, pharmacists often are qualified by the PBM to perform and be reimbursed for cognitive services after attending continuing education seminars on targeted disease states. Qualified pharmacists are reimbursed for counseling patients identified by the PBM as overusing inhalers on the proper use of medications and inhalers and answering patients' questions about their drug therapies. The pharmacist may also talk to the patient's physician to recommend an inhaled steroid rather than an inhaled beta2-agonist; if a change is effected, the pharmacist receives additional compensation.

Cognitive services reimbursement

About half of the surveyed PBMs are reimbursing pharmacies for cognitive services (see Table V.8). In many cases, cognitive services reimbursement is still in the experimental stage; for example, it may be part of a new disease management program that has been implemented for a few clients. Cognitive services reimbursement may be offered only to those clients using restricted or performance-based pharmacy networks because pharmacists in these networks have been qualified to perform "special" services. Other PBMs expressed the view that they were able but unwilling to reimburse pharmacists for the provision of cognitive services. PBMs owned by chain drugstores may not have to supply financial reimbursement for cooperation by their chain's pharmacists in cognitive services programs, if corporate policy dictates the provision of these services. In other instances, some chain drugstores have a history of paying "bonuses" to pharmacists if the pharmacy reaches a certain level of generic dispensing; PBMs indicated a preference for contracting with such providers.

Lack of PBM client support

Obtaining client support for cognitive services reimbursement is a major challenge for many PBMs. Clients resist paying additional charges for this activity because they believe that cognitive services "used to be performed for free," are required under law, or do not produce desired results. As a result, some PBMs are paying for cognitive services themselves until their evaluations can demonstrate to clients that cognitive services programs can improve patient care and positively affect drug costs and total health care expenditures.

Some PBM clients indicated that they are in the planning stages for cognitive service reimbursement programs with their PBM or other entities, e.g., the American Pharmaceutical Association. The *Ciba Pharmacy Benefit Report* (1995) states that 7.5 percent of health plans are paying pharmacies for professional services, such as counseling patients with certain medical conditions; almost ten percent plan to begin such payments in 1996. An even greater number of health plans (18.9 percent) are reimbursing pharmacists to discuss with physicians the appropriateness of prescribed drugs -- more than twice the number of health plans compared to 1994.

Documentation

PBMs require documentation that a pharmacist has performed a cognitive service through an online claims submission (e.g., using an NCPDP professional services code) and possibly written confirmation from the patient (for example, a postcard filled out at point-of-sale). Another type of documentation required is the development and maintenance of a pharmaceutical care profile.

Payment

Cognitive services are reimbursed at various levels depending on the type of intervention. Among the PBMs studied, the highest payment a pharmacy could receive ranged from $7 to $15. In one case, the PBM incrementally paid a maximum of $15: $6 for recommending a change in therapy; an additional $6 if physician adds the preferred drug therapy; and an additional $.50 for up to 6 refills of the preferred drug therapy. Other payments are made for extensive patient counseling on appropriate drug use, such as in a disease management program. Payment is made whether or not a therapy or drug use change occurs, as long as the counseling is documented.

Payment for cognitive services is made to the *pharmacy* -- attenuating the *pharmacists'* incentive to perform or document the provision of cognitive services. Some interviewees suggested that pharmacies could encourage performance and documentation of cognitive services with financial incentives for the employee pharmacists.

Barriers to pharmacy participation

PBMs reported "disappointing results" with cognitive services reimbursement to pharmacists but did not wish to elaborate with specific data. Interviewees acknowledged that pharmacies are under incredible pressure to produce volume, in terms of number of prescriptions dispensed, and sometimes lack the time for provision of cognitive services. Yet, several PBMs believed that cognitive services offer community pharmacists a needed opportunity to demonstrate their value:

> *"[The PBM] industry is giving pharmacy an opportunity to move ahead, but instead we are being defined as the enemy."*

PBMs noted the importance of obtaining pharmacies' commitment to cognitive services programs in advance, to avoid sending pharmacies large amounts of educational materials which may be ignored. Some PBMs discussed continuing education programs (CE) which pharmacists must complete before being reimbursed for provision of cognitive services.

Pharmacists had their own perspective on lackluster participation in cognitive services programs. They felt that PBMs misused "cognitive services" provided by pharmacists to shift market share to rebated products, for the PBM's (and/or plan sponsor's) financial gain. Pharmacists believe that cognitive services should involve the use of their professional judgment, rather than the enforcement of preferred product lists. Pharmacists also complained that the paperwork required to document cognitive services was onerous to complete, particularly given the time pressures they face with increased dispensing volumes. Pharmacies dislike the expense of upgrading their computer systems (if necessary) in order to submit cognitive services claims to a PBM.

Measuring effectiveness

Because many cognitive services programs are new, very few PBMs have measured systematically their effectiveness in reducing costs and improving quality. One PBM mentioned that it examines the impact of its cognitive services reimbursement on drug costs, but it did not explain its methodology for calculating impact. Another PBM tracks the number of pharmacist-patient counseling documentations received and compares it to the number of patients identified as eligible for counseling. However, the PBM added that it does not measure the results of cognitive services programs by examining percentage of prescription reversals or similar activities.

One interviewee at a large health plan expressed frustration with difficulties encountered in evaluating the quality and results of cognitive services provided by pharmacists. He believes that ideally, pharmacies would be selected for networks based on the quality of their cognitive services, rather than on their acceptance of discounted AWP formulas. If cognitive services could be evaluated accurately, fewer pharmacies would be included in the network; "I don't need 850 pharmacies, only 450 are really necessary -- but I cannot measure performance on cognitive services."

Fraud

PBMs mentioned that if Medicaid and other payers are to explore cognitive services reimbursement, they would have to address the potential for fraud, i.e., pharmacies submitting claims for services which did not occur, or reversing (and then re-reversing) prescriptions to capture the cognitive services fee. Although a relatively rare occurrence, one PBM noted that to avoid fraud of this nature, it controlled which high utilizer/high risk patients were eligible to receive counseling services, rather than allowing pharmacies to identify patients.

Table V.8
Cognitive Services Reimbursement

PBM	Cognitive services reimbursement programs
•	Yes, pharmacists in performance/selective network are paid for responding to P-DUR messages and making a change in therapy or for patient counseling. Documentation via NCPDP codes.
•	Yes, within performance/selective network for patients in seniors program, disease management program, and DUR. Pharmacists are paid for "anything other than dispensing," including their dispensing fee when claim is reversed. Pharmacist and patient submit documentation (NCPDP code).
•	Yes, within performance/selective network. Pharmacists are paid for patient education and drug interchange.
•	Yes, cognitive services reimbursement is in experimental stage and is part of new disease management program. Pharmacists are reimbursed for patient education. Documentation is entered online and patient fills out form.
•	The PBM is owned by a chain pharmacy which can impose the services on employee pharmacists regardless of payment offered by PBM.
•	No cognitive services reimbursement.
•	No cognitive services reimbursement.

2. Retrospective and Prospective Drug Utilization Review (DUR)

Drug Utilization Review (DUR) is conducted to improve the cost-effectiveness and quality of patients' drug therapies. For the PBMs interviewed, the DUR function occurs primarily within the framework of formulary management. Within the PBM context, the main goal of DUR is to reduce costs through increased use of formulary drugs and to prevent adverse health outcomes which may increase overall health care costs.

Medicaid Drug Utilization Review (DUR) Annual Reports

A review was conducted of DUR annual reports submitted to HCFA by state Medicaid agencies to help us compare the status of DUR in Medicaid to its use in PBMs. In these reports, states are required to include evaluations of the cost savings of their drug utilization review programs. A review of FY 1994 Medicaid DUR reports to HCFA identified the status of P-DUR implementation and R-DUR implementation; and identified the estimated savings, the evaluation methodology, and the evaluator of any evaluations submitted. Reports from 42 states were available for review at the time of the study. Missing reports were Arizona, California, Montana, New York, Ohio, Oklahoma, Tennessee and Virginia. In Arizona and Tennessee all beneficiaries were enrolled in managed care plans.

Of the 42 state reports reviewed, all but five had implemented their R-DUR program by 1993 and 12 had implemented their R-DUR programs prior to enactment of OBRA '90, the legislation mandating DUR in all Medicaid programs (see Appendix D). While OBRA '90 does not require states to have an online, P-DUR program, nine states had operational online, P-DUR programs in 1994; 15 planned to have such programs operational in 1995; and 13 in 1996 or later. Five states had no plans for online P-DUR. Most states contract with an outside vendor to develop and manage their P-DUR and R-DUR programs. By comparison, 95% of PBMs reported having online P-DUR capabilities and a similar percent reported having R-DUR programs .

OBRA '90 also required states to estimate the cost savings attributable to R-DUR and P-DUR. HCFA provided guidelines for evaluation (US DHHS, 1994) to improve the rigor and uniformity of the evaluations. A review of 1993 Medicaid DUR reports found that few states provided estimates of savings (APhA Foundation, 1995). Some of these early estimates were derived from the use of questionable research methods with few states using control groups.

In our review of the 1994 DUR reports, 26 of the 42 states reported evaluation results of their DUR programs. Most evaluations were performed by the DUR vendor and consisted of pre-post designs without a comparison group. Few states had substantial experience with online P-DUR and estimates of P-DUR cost savings were provided by only three states. Maryland estimated its annual P-DUR savings at $8.9 million dollars with $6.2 million related to denial of claims with an early refill and the remainder due to

claims that were reversed (i.e., not paid) after a DUR alert. Although HCFA guidelines cautioned states about assuming claims denied or reversed are not paid later or are replaced by another drug, Maryland did not examine whether early refill denials were filled later or denials reversed. Oregon and New Mexico reported savings, but did not provide their methodologies for calculating the savings.

The most common intervention used in R-DUR was a letter to prescribers and pharmacies outlining potential problematic drug use. In their evaluation of R-DUR, three states (Idaho, Wisconsin, Washington) used control groups when estimating DUR savings for letter interventions. The treatment group received a DUR letter regarding the questionable drug use, whereas the control group did not receive a letter. Wisconsin reported on two letter interventions ("excessive use" of ulcer drugs, concurrent use of sucralfate and other ulcer drugs) with estimated total annual savings of $48,812. Washington reported on one intervention that produced a modest change in physician prescribing practices, without any estimated savings. Idaho conducted a study of 52 high prescribers of ulcer drugs, matched with 52 randomly selected prescribers who also were high prescribers of ulcer drugs. The report provided no estimate of cost savings, but described a greater decrease in "excessive use" in the intervention population than in the control population.

Michigan selected physicians with high targeted drug use for a face-to-face intervention and randomly selecting from these physicians for a comparison group. They reported an annual estimated savings of approximately $1,000 for each of the 77 physicians visited. Wisconsin selected physicians with high nonsteroidal anti-inflammatory drug use for a face-to-face intervention. A comparison group was drawn from the sample of physicians. Wisconsin reported an estimated six-month cost savings of $420 for each of the 57 physicians visited. Alabama conducted an evaluation letter intervention that used prescribers who did not receive a DUR letter as the comparison group. They reported an annual estimated savings of $1,424,174. The remaining states used pre-post study designs without a comparison group. They reported estimated cost savings ranging from $6,513 in Alaska to $4.4 million in Louisiana (see Appendix E).

In those states with control groups, estimated cost savings projected from R-DUR programs were either modest or nonexistent (e.g., $48,812 in Wisconsin for ulcer drugs, and "modest" unquantified savings for Idaho and Washington). These findings suggest that the biases and limits inherent in the weak research designs characteristic of the other state reports tend to exaggerate the effects of R-DUR programs.

Other interventions, conducted in Michigan and Illinois, involved pharmacists or physicians telephoning prescribers to discuss potential prescribing problems identified through computer review. Michigan estimated a savings of $132,283 for the phone intervention. No control group was used in the evaluation, but an arbitrary adjustment for Regression to the Mean was made in this pre-post study. No evaluation results were available for the Illinois phone interventions.

Comparisons between PBMs' and Medicaid's R-DUR programs were difficult due to data problems and limitations in each program. Most PBMs did not provide DUR cost savings data to the research team. Further, most Medicaid evaluations suffered from low response rate, poorly controlled research designs, inadequate cost-savings methodologies, and potential bias inherent in vendors performing analyses of the success of their own programs, rendering interpretation of the data highly questionable. Thus, systematic comparisons of DUR cost-effectiveness between PBMs and Medicaid could not be conducted.

Retrospective Drug Utilization Review (R-DUR)

Most PBMs offer R-DUR, either as part of the recommended, standard package, or as an "add-on" service for plan sponsors who desire a more comprehensive package. In many instances, it was difficult to determine the actual number of covered lives receiving R-DUR services under PBM benefit packages. Several PBMs reported that only a small proportion of their contracts included R-DUR, or that it was performed on a "case-by-case" basis for "larger clients." Other PBMs reported that from 70 to 100 percent of clients received R-DUR services.

Almost all PBMs performing R-DUR do so "in-house," although one reported using an outside vendor while it developed in-house capability. PBMs typically use (after modifications) a commercially available database for R-DUR and other PBM activities. This database integrates pharmacy claims data from retail and mail order pharmacies, although a small PBM noted that its database did not contain mail order claims because they represented a very small fraction of its total business.

One PBM distinguished R-DUR performed at the metropolitan statistical area (MSA) level versus client-specific R-DUR. The MSA approach enables clients who do not have a tightly defined physician network, or whose covered lives do not account for a substantial proportion of physicians' practices, to increase their clout with physicians by being bundled with other clients in their MSA. The PBM asserts that this approach increases the validity of the data extrapolated from R-DUR, increasing the likelihood that physicians will respond positively.

Development of DUR criteria and algorithms[15]

One PBM described in detail its DUR criteria development process,[16] which utilizes both nationally-available clinical criteria (e.g., First Data Bank) and proprietary clinical criteria. The criteria are evaluated by independent experts and the PBM's national

---

[15] *Criteria* are predetermined elements of drug use against which aspects of quality, medical necessity, and appropriateness of drug use may be compared. *Algorithms* are the step-by-step rules for applying the criteria to the data to arrive at the exception.

[16] The DUR criteria development process described here also applies to prospective DUR.

P&T committee. The PBM recommends standard DUR criteria to the client, but some clients, particularly Medicare and Blue Cross and Blue Shield organizations, request customized criteria to target specific concerns (e.g., limiting the use of H_2 antagonists in specified circumstances). The PBM does not implement the DUR criteria until they have been refined to limit false positives, by testing with a statistically valid sample of patients and carefully identifying factors which are associated with false positives. R-DUR letters (or P-DUR alerts) are not generated if these factors appear in a patient record which otherwise would prompt an alert message. Once clinicians develop DUR criteria, they are implemented by systems management analysts. According to the PBM, this "marriage" of clinical and strategic skills has been an effective model to achieve change in prescribing and dispensing patterns.

Interventions implemented by PBM or plan sponsor

PBMs report using a wide range of interventions to change physician behavior after R-DUR has identified an inappropriate prescribing practice. Some PBMs identify patients, physicians, or pharmacies as targets for interventions and turn this information over to their client. For example, PBMs may work primarily with their managed care clients' Medical Directors on R-DUR, supplying quarterly information to clients who direct education and case management activities in-house. If the client is a Medicaid program, the contract may stipulate that the PBM transfers data to the state, which then handles the R-DUR activities in-house or through a separate subcontractor. On the other hand, not all PBM clients wish to receive name-specific information collected through R-DUR, such as names of physician outliers, preferring to allow the PBM to handle communication with patients, physicians, or pharmacies.

Physician-level interventions

Written correspondence with physicians is the most common intervention applied by the PBM. These letters include peer comparisons, patient profiles, and educational information on targeted drugs or disease states. In some cases, physician correspondence is conducted as part of new disease management initiatives, although it may fall into the broader category of DUR.

All PBMs asserted that the development of physician profiles was part of R-DUR, although many did not elaborate on this activity. These profiles are only as accurate as the information (e.g., physician identification numbers and specialties) provided by insurers. Profiles are mailed to physicians so that they may compare their performance on generic or formulary prescribing and use of high-cost medications to peer groups. Two PBMs further noted that comparisons within a physician's specialty could be provided.

DUR letters also serve an educational purpose by targeting inappropriate prescribing patterns, e.g., incorrect dosages or durations of therapy for a certain drug.

PBMs tend to emphasize over-utilization versus under-utilization of drugs, although one PBM stated that the installment of better information systems linking pharmacists and physicians to patient drug records would facilitate assessments of under-utilization.

Letters to physicians often contain patient-specific information, such as the names of patients taking a high-cost medication targeted by the PBM, a profile of all drugs prescribed for certain patient, or a warning about a possible drug-drug, drug-disease, or drug-age interaction. The letters list alternative lower-cost or formulary drugs. One PBM asserts that R-DUR is most effective when a patient-specific letter is sent and inserted by the physician into the patient's chart to act as a reminder about preferred drugs. The letter includes an area for the physicians to record their responses to the intervention which is sent back to the PBM. The PBM reports that for 40 percent of letters sent, physicians fill in the response section of letter and return it to the PBM. One unresolved issue is determining the proportion of physicians who ultimately change their prescribing practices.

Several PBMs mentioned "academic-detailing" of physicians that frequently prescribe costly and/or nonformulary drugs, or prescribe incorrect dosages or durations of therapy. Academic-detailing occurs by telephone or in-person visits, sometimes provided by pharmacists employed by the PBM who are assigned to work with specific clients or in specific geographic areas.

Pharmacy profiles

All PBMs reported that pharmacy profiles are prepared as part of R-DUR. Typically, these profiles are mailed to pharmacies and PBM clients on a quarterly basis. Many PBMs call pharmacies to discuss the results of R-DUR activities. Outliers are targeted for educational follow-up and, perhaps, audits.[17] One PBM noted that outliers who do not respond to interventions may be dropped from the network. Another PBM established regional panels of pharmacists to which community pharmacies' profiles are mailed. These pharmacy panels are responsible for intervening with community pharmacists to effect changes in dispensing behavior.

Patient-level interventions

Direct contact with patients varies from PBM to PBM, and within a PBM from client to client. Several PBMs identify patients to their plan sponsor or to the patient's physician, who are then responsible for DUR interventions. Direct contact initiated by PBMs with patients may occur as part of disease management programs, e.g., pharmacists are alerted to contact certain patients who have been identified as asthmatic through a review of drug claims.[18] One PBM described a compliance program in which PBM staff

[17] PBM contracts with pharmacies stipulate that the PBM has authority to perform audits.

[18] Most PBMs do not have access to patient diagnostic data, which would allow more accurate identification of eligible patients compared to claims data. However, some PBM clients are sharing diagnostic data with their vendor on a pilot program basis.

call patients, particularly those starting a new drug therapy, to encourage compliance and to discuss side effects or other problems. Some PBMs send newsletters to patients directly. One PBM's methodology includes sending patient self-assessment surveys; information on diagnoses or allergies helps inform both DUR and disease management processes.

Results

One PBM reported results with R-DUR over a one year period -- 6 percent of claims receive medical intervention at the patient level and between 10 and 15 percent receive intervention at the physician level. Other PBMs did not reveal R-DUR results for a variety of reasons: the data are proprietary, the data are variable from client to client so it is difficult to report "average" results, and/or the data are not analyzed systematically. Several PBMs commented that the ultimate success of R-DUR -- changing physicians' prescribing practices -- rests with the effectiveness of the intervention designed to bring about behavioral change.

PBM client perspective

Clients reported that PBMs collected baseline prescription claims data before implementing an R-DUR program; presented recommendations for target R-DUR areas, e.g., prenatal care, immunizations, and diabetes; made comparisons to other clients' experiences with R-DUR programs; and conducted cost-benefit analyses to demonstrate that the savings achieved would offset the costs of implementation.

Clients believed that letters to physicians which addressed specific disease states and/or patients were more likely to be successful than general letters. They also addressed R-DUR's limitations and noted that not all clients are willing to pay additional charges for R-DUR:

> *"In terms of R-DUR, we have similar problems interpreting changes in utilization as we do with [P-DUR] -- are changes a result of the intervention, or are they the result of changes in benefit design or patient population? If we wanted [our PBM] to do a rigorous analysis to determine the effectiveness of R-DUR, we could ask them to do it, but we would have to pay for it!"*

R-DUR performed in Medicaid programs

Interviewees conjectured that Medicaid programs may have an advantage compared to PBMs, in that they have access to medical claims data which can inform DUR interventions. Access to medical claims data also enables better evaluations of the

DUR interventions' impact on quality and costs. In contrast, PBMs must obtain cooperation with clients for access to these data. One Medicaid expert interviewed believed that R-DUR programs provided by Medicaid and PBMs were, on average, equally competent. It is important to note that Medicaid agencies *per se* may not be providing R-DUR because they often contract management of the R-DUR program to outside vendors.

Prospective Drug Utilization Review (P-DUR)

PBMs generally defined P-DUR as identification of a drug-therapy problem in advance of dispensing and monitoring of the problem at the pharmacy level. With the exception of one PBM which "outsources" most claims processing and DUR activities, all PBMs provide in-house, online claims processing and P-DUR (PBMs often use the term *concurrent DUR* or *C-DUR*). All PBM covered lives on the claims processing platform typically receive P-DUR, although occasionally indemnity clients may provide a PBM with only employee information (rather than patient-specific data on spouses or dependents), thereby prohibiting online DUR. Most PBMs use First Data Bank or similar data analysis systems with their own modifications.

Interviewees stressed that on-line, point-of-service claims processing and P-DUR represent a great advance in PBM capabilities, allowing prescriptions to be expeditiously authorized and adjudicated against the patient's drug profile. Several interviewees mentioned that Medicaid programs which had not yet transferred administration of their pharmacy benefit to online systems would be wise to do so as quickly as possible. The main problem associated with P-DUR is that the alerts generated are only as accurate as the data entered into the system. Computer data entry errors (e.g., wrong age or sex) cause the DUR system to flag problems which do not exist.

The P-DUR systems alert pharmacists to potentially dangerous drug-drug, drug-age, drug-sex, drug-pregnancy, interactions, early refills, therapeutic duplications, and in rare instances, "refill too late," which might indicate underutilization. The flags are usually transmitted to the pharmacy according to a hierarchy, with priority given to the most severe warnings. Many PBMs stated that their systems were set to flag only a high level of severity, due to an otherwise excessive incidence of false positive alerts. One PBM noted that "False positives are not out of control." However, some interviewees disagreed with this statement, and asserted that a high incidence of false positives makes pharmacists less willing to respond to alerts.

Access to other databases

Typically, access to P-DUR is restricted to the pharmacy claims database, although several PBMs are planning to incorporate medical claims data in collaboration with some of their most "proactive" large clients, typically HMOs and Blue Cross and Blue Shield plans (see Disease Management section).

Only one PBM reported that pharmacists did not have access to patients' pharmacy claims histories. However, PBMs pharmacy claims "histories" only contain data accumulated during the patient's enrollment in the PBM. The high levels of "churning" characteristic of the current PBM market (see PBM Clients section) limits pharmacists' access to historical patient data covering a prolonged period of time.

Proportion of DUR alerts resulting in pharmacist action

PBMs' ability to track actions resulting from a DUR alert varies widely, although many are not capable of tracking the progression of activities prompted by an alert. One PBM reported that a new computer system has enabled it to track DUR actions taken by pharmacists, and another is encouraging pharmacists to code reasons when a DUR alert is ignored. More typically, PBMs report to clients limited information, such as the total number of DUR alerts generated for their covered lives and the number of resulting denials or reversals. PBMs may offer reports on actions resulting from P-DUR alerts only as part of "enhanced" DUR packages (which apply to relatively few covered lives and constitute an added cost to PBM clients). The number of prescription denials and reversals is used to calculate the savings achieved through P-DUR, although calculations may be flawed if the PBM does not account for prescriptions which are later filled.

One PBM reported that 35 percent of claims trigger an alert; another reported that 28 percent do. One PBM reported that "10 percent of prescriptions are potentially hazardous and require DUR action." PBMs reported that from 0.8 to 3 percent of prescriptions are reversed under P-DUR, primarily for therapeutic duplication.

One reason why few DUR alerts result in action by the pharmacist may be the prevalence of "soft edit" warnings. Soft edits are flags to the pharmacist that a potential problem exists; they do not block adjudication of the claim. Many plan sponsors do not want their PBM to implement "hard edits" which would reject the prescription unless the pharmacist contacted the PBM to approve an override. Some PBMs are beginning to have pharmacists enter reasons for ignoring flags in order to monitor P-DUR effectiveness. Hard edits are becoming increasingly common; however, they are not uncommon for "refill too soon" and prescriptions which exceed maximum daily dose. One PBM noted that it recently has begun rejecting prescriptions when the P-DUR system flags a drug-drug interaction where the potential for serious harm is high. If the implementation of these hard edits is successful for the several large clients involved in the test program, it will be implemented more broadly. The trend towards greater use of hard edits may reflect, in part, soft edits' ineffectiveness in stimulating action by pharmacists.

Several PBMs complained that plan sponsors are more focused on the dollar value of the savings achieved through P-DUR, rather than the potential for clinical management offered by the P-DUR system. In particular, plan sponsors with high enrollee or employee turnover (e.g., HMOs, service industry) may be less interested in DUR than clients who

retain their employees for many years. One PBM interviewee stated that Medicaid programs have been focused on reducing drug costs through DUR, with too little regard for the potential impact on overall medical care expenditures.

Pharmacist incentives and support

Several PBMs are implementing pilot initiatives to offer incentive payments to pharmacies when pharmacists respond to DUR alerts, for attempting to contact the physician, and a greater incentive for obtaining approval for a prescription change (see section on cognitive services). These initiatives may apply only to clients who chose "enhanced" services plans.

One PBM reported that its contracts with pharmacies contain language requiring pharmacies to act on DUR alerts, and outliers face the risk of being dropped from the network. While several PBMs mentioned that these types of penalties may become more common, P-DUR response requirements and the enforcement of other resource utilization standards are currently rare.

Two PBMs operate call units which pharmacists may contact if they do not have time to call a physician in response to a DUR alert. These units are "virtual pharmacies" where pharmacists also conduct therapeutic interchange and generic substitution.

Innovation in DUR

PBMs asserted that they are attempting to create new approaches to drug utilization review to meet cost-cutting goals while improving quality and clinical outcomes. An interviewee at a large PBM emphasized that clinical interventions, such as DUR, rather than administrative functions, will receive increased attention in the future:

> *"Interventions are the focus of future strategy. We want to become 'Intervention, Inc.'"*

One PBM asserted that integrating P-DUR and R-DUR functions may optimize their value; problems identified through R-DUR can be targeted for P-DUR interventions. For example:

> *"For example, a major rule in R-DUR is concerned with long-term use of H_2 antagonists. There is no reason why this rule can't be incorporated into concurrent DUR as a reject. Some of our more proactive managed care clients are requiring us to move R-DUR rules into P-DUR."*

Several PBMs are developing or currently offering clients access to drug claims databases to retrieve information on drug utilization organized by patient category,

physician, or drug therapeutic class. The information can be downloaded to clients' own computers.

PBM client perspective

Clients discussed the difficulty of measuring P-DUR programs' results:

"Our plan measures prescription reversals as 'success' but does not track when other medication is prescribed after a reversal. [Our mail order pharmacy vendor] is the dispensing pharmacy so they know what happens after the alert. But [our retail-sector PBM vendor] just processes data; they don't have the ability to connect a DUR alert to the drug that is ultimately dispensed to the patient."

"We lack a good control for our interventions -- did the change result as a result of the intervention, or something else?"

Clients noted that the analysis of P-DUR programs was limited not only by PBM systems capacities, but also because PBM clients may not have staff pharmacists and data managers to analyze and react strategically to DUR reports.

One health plan with a large number of Medicaid enrollees noted that its PBM has a broader P-DUR system than the state Medicaid P-DUR system. The health plan's pharmacy director noted that the state's approach -- limiting the number of target therapeutic classes -- reduces the number of false positive alerts transmitted by the P-DUR system. Nonetheless, the pharmacy director is confident that the PBM's system has not triggered a burdensome number of alerts. He stated that an additional benefit gained by using a PBM has been use of its pre-existing infrastructure for P-DUR, compared to otherwise large financial investments in computer systems.

P-DUR performed in Medicaid programs

A Medicaid expert reported that small states' Medicaid programs are less likely to have online P-DUR programs, stating that pharmacists in these states perform P-DUR at point-of-sale without the aid of online systems. However, large states -- which account for the majority of Medicaid recipients -- have online P-DUR systems and are measuring their impact. The state programs have hard edits in place and examine drug therapies that are denied. Some states do not want to invest in on-line, point-of-sale systems because they are moving recipients into managed care plans which will manage the pharmacy benefit. There is opportunity for PBMs to expand P-DUR to the remaining state Medicaid programs that currently lack online systems (see Appendix D). Unanswered questions

remain about the ability of P-DUR systems used by PBMs and Medicaid programs[19] to achieve cost savings and improve quality of care for Medicaid recipients.

While PBMs' technology may be more advanced than Medicaid's, some interviewees expressed concern that PBM P-DUR systems transmit too many false positive alerts. One interviewee believed that Medicaid programs tend to produce fewer alerts overall (and, therefore, fewer false positive alerts) since unlike PBMs, they are not attempting to impress clients with large numbers of DUR alerts. A report by the General Accounting Office (GAO) on P-DUR in five state Medicaid programs reports that 20 percent of drug claims resulted in an alert and 2 percent of all claims were reversed as the result of the alert (GAO/AIMD-96-72, 1996). As noted earlier, PBMs interviewed for this study reported P-DUR "hit rates" of 28 to 35 percent.

R-DUR and P-DUR Results

Reports to PBM clients

The types of data collected to evaluate DUR depends on the plan sponsor's interests. For example, clients will request information on the utilization of a certain drug or drug class, the global number of alerts transmitted, and/or the incidence of specific drug-therapy problems (most often overutilization, therapeutic duplication, and drug-drug interactions). One PBM's enhanced DUR program measures changes in therapy and the cost impact of DUR actions, and the time between alert transmittal and pharmacist response (i.e., resubmission) or no pharmacist response. Other PBMs stated that new computer programs will improve their ability to track actions by pharmacists and physicians in response to DUR transmitted at point-of-sale.

The value of reports submitted to PBM clients would be maximized by the development of a standard "report card." HEDIS may be a vehicle through which future improvements in reporting are made. What levers, if any, do Medicaid programs, private employers, and insurers have to demand standardization of DUR criteria and systematic reporting of DUR effectiveness? Can the purchaser withhold a percentage of its PMPM unless PBMs produce changes in physician prescribing, as measured by HEDIS?[20]

Evaluation of results

Most PBMs' explanations of the methodologies used to evaluate DUR results were vague. Several stated that results were evaluated "indirectly" by examining changes in drug prescribing or utilization pre- and post-intervention, and by examining changes in

---

[19] See DUR literature review for a brief description of two HCFA-funded demonstration projects designed to examine the impact of P-DUR on Medicaid recipients under OBRA '90.

[20] Pacific Business Group on Health (PBGH) is withholding 2 percent of California HMOs' premiums unless they perform at certain targeted levels on a dozen HEDIS indicators

prescribing and dispensing trends at the level of physician, pharmacist, or region. However, given the absence of a control group, any changes could be due to factors other than the DUR interventions.

One PBM representative is concerned about the expense associated with comprehensive measurements of DUR results:

> *"The cost of measurement (controlled longitudinal study) is going to be more than the savings generated by the program."*

If this cost assessment is correct, linking medical and pharmacy claims data (see Disease Management Section) may not be the only barrier to the conduct of rigorous outcomes research.

The value of DUR in PBM and Medicaid settings

Some PBM interviewees discussed the need to integrate DUR with other aspects of pharmaceutical care and management. They noted that PBM clients, including Medicaid programs, must realize that DUR is not only a cost saving mechanism, but also has the potential for improving the quality of care and patient outcomes, especially when used in conjunction with other drug management techniques (e.g., therapeutic interchange).

PBM clients and others would argue that rigorous data analyses demonstrating cost savings have not been published such that they may be independently substantiated. The results of P-DUR alerts sent to pharmacists are often not tracked, and the ability of physician interventions to create permanent, long-term changes in prescribing behavior is unproven. If PBMs can demonstrate the value of their DUR programs, client demand for them may intensify. Until such time, Soumerai and Lipton's question, "Drug Utilization Review: Benefit, Risk, or Boondoggle?" cannot be answered.

Comparisons between DUR conducted by PBMs and DUR conducted under Medicaid are tentative at best. The research team was unable to obtain quantitative results from DUR programs conducted by the PBMs. Most PBMs shared little detail about DUR criteria and program implementation. Additionally, several PBMs did not consider retrospective-DUR as a service normally provided as part of the core benefit. Thus, a comparative analysis of DUR performed in PBM and Medicaid settings awaits future research.

3. Disease management programs

About 5 percent of the U.S. population uses about 50 percent of health care spending each year, and about 20 percent uses about 80 percent of health care spending. Among these high-expense populations are important subgroups of patients with chronic

conditions, which usually require the use of drugs. The promise of disease management initiatives is that new efforts to target such patients may produce better health outcomes and lower total health costs (Etheredge 1995).

Disease management assumes a comprehensive, integrated view of disease, focusing on chronic, high-cost medical conditions where pharmaceuticals play a critically important treatment role. Traditional medicine treats an illness in one setting and specialty at a time, whereas disease management treats a disease across the continuum of care: from wellness to critical condition; from prevention to tertiary care; from home to hospital. Designed to prevent acute episodes, disease management works proactively to educate patients and assure compliance and to educate physicians and improve prescribing and other clinical practices. Proponents say that disease management fulfills the promise of managed care by managing the quality and process of care, not just containing costs (Borzo 1996). A health care consulting firm defines disease management as follows:

> *. . . a comprehensive, integrated approach to care and reimbursement based on the natural course of a disease, with treatment designed to address the illness by maximizing the effectiveness and efficiency of care delivery. The emphasis is on preventing disease and/or managing it aggressively where intervention will have the greatest impact (The Zitter Group, San Francisco, CA 1994).*

Extent of PBM use of disease management

According to a recent survey by SMG Marketing Group, Inc., disease management services are offered by almost 50 percent of PBMs. The report states that the increasing reliance on disease management programs by PBMs is in alliance with strategies being used by drug manufacturers: "Both are expected to use outcomes research and disease management to target smaller high-risk groups of patients with diseases requiring ongoing high-drug usage" (Jackson 1996).

Disease management programs at PBMs studied

All PBMs interviewed were developing, piloting, or initiating disease management programs at the time of the site visits. Most programs were in various stages of pilot testing or being finalized for production; one PBM reported having programs in "full production." Given the developmental or new nature of the programs, they typically cover a relatively small percentage of PBMs' covered lives. Some PBMs are in the process of establishing a more selective network that will train pharmacists in the care of diabetic and asthmatic patients. They plan to reimburse two or three pharmacies in a region to provide disease management services. Many PBMs expressed that belief that disease management is the future of health delivery systems. The importance of disease management is evidenced by surveyed PBMs making significant capital investments in information technology systems designed to improve disease management capabilities. Vertically

integrated PBMs are particularly likely to make major investments in information technology and to integrate disease management as a pivotal component of their strategic thinking.

Asthma, depression, and diabetes lead the list for PBM disease management initiatives, largely because improved compliance with self-management practices, prescriber adherence to best practices and appropriate drug utilization can result in cost savings (e.g., decreased diagnosis-related emergency room visits) (Etheredge 1995).[21] PBMs also are offering disease management programs in gastrointestinal disease (targeted toward appropriate h pylori testing and antibiotic use, with expected decreases in use of H2 antagonists; and reduction in prescribing of H2 antagonists from therapy for active disease to maintenance dosing). Some PBMs are offering disease management programs for hyperlipidemia using a fully integrated cardiovascular approach. Additional programs, such as hypertension and osteoporosis, will be launched in 1997. Although the interventions are currently available to customers, the overwhelming majority of these programs are not in full production. Hence, at this point in time they affect a very small percentage of PBMs' covered lives.

To communicate their disease management interventions, PBMs employ direct mailings targeted primarily to patients. They also distribute drug use treatment guidelines to physicians in which step protocols are followed, i.e., older, less expensive drug agents are the initial choice of therapy. Further, physicians are sent drug information in the form of newsletters, educational booklets, interactive workbooks, videotapes and letters. Other communications, used less frequently, include telephone calling from pharmacists to physicians, online physician and pharmacy networks, and personal contacts between pharmacists and patients.

In several instances, disease management programs require participation in continuing education courses by community pharmacists and reimbursements for pharmacists' patient counseling efforts (payment ranges between $5 and $10 per intervention). More typically, the disease management programs focus on educational materials sent to targeted patients who have expressed interest in participating in the program. The focus is on self-management strategies for chronic diseases including, but not limited to, lifestyle and behavioral changes with respect to diet, exercise, and appropriate use of medications.

Some PBMs employ an explicit disease management strategy to interest plan sponsors in these programs:

> *"With some disease states, you can optimize drug therapy (e.g., use of ace-inhibitors and antihypertensives) and get really quick results -- within 90*

[21]It has been estimated that treatment of asthma, ulcers, and diabetes accounts for one-quarter of employer health care spending. Source: Interview with P. Roy Vagelos, *Harvard Business Review*, November/December 1994, as reported in Etheredge (1995).

days. We start a client with one of these programs to win them over. The next step is a disease management strategy involving asthma compliance type program, where results will be apparent after 180 days. The final step is a diabetes program where results are long term. HMOs may not be interested [because of the high turnover of enrollees], but many employers are interested because they see a diabetic as a 20-year commitment."

This latter finding is born out in the results of a recent Mercer study which found that a vast majority of large employers plan to control drug costs by installing integrated disease management programs within the next two years. About 77 percent of surveyed employers said that they would likely pursue such an arrangement (*Managed Pharmaceutical Report.* April 1996:10).

There is wide variation in how PBMs are paid for implementation of disease management programs. Such programs are not part of the typical package of services offered to most clients. Generally, if clients desire disease management services there are additional charges for these programs; however, several PBMs are piloting disease management programs for large clients (typically HMOs), and in some instances, these joint activities between the health plan and PBM is viewed as "beta testing" the disease management program and the health plan does not pay the PBM for the program until the results are measured and proven. In other instances, disease management services are provided on a risk-sharing basis. For example, even though the PBM charges its clients for these programs, it may provide savings guarantees, i.e., promises to clients that if these programs do not lower associated physician and hospital costs, then the PBM will lower its overall bill accordingly (*Business and Health Special Report* 1995:18).

Reactions among PBM clients to disease management programs ranged from skepticism to cautious optimism. Those plan sponsors having misgivings about disease management programs developed these views out of negative experiences or concerns about the objectivity of vertically integrated PBMs:

"The PBM instituted a few disease management programs, which were only geared toward saving them money and obtaining rebate dollars. The PBM was not looking at the total patient. After our contract was re-negotiated, we started to supply the PBM with medical data, but I still have not seen any results of the use of these data."

"The 'Big Three PBMs' and the pharmaceutical companies which own them have access to resources, both financial and clinical, which they could make available for successful disease management programs. But I have concerns about whether prescribing patterns would be inappropriately influenced. Monitoring is necessary to prevent this."

Most interviewees expressed a "wait and see" attitude toward disease management programs:

"We hope that disease management will save us money, but we do not know what

we're getting into, so we are not committing to extensive or expensive programs at the outset. With the asthma program, we're hoping to decrease emergency room visits, and with the GI (gastrointestinal) program we hope to reduce drug use."

One managed care spokesman questioned:

"Why should we pay PBMs for disease management? We have no idea whether it works!"

Quality aspects of disease management programs: Measurement of clinical outcomes

About half the PBMs studied are assessing pharmaceutical therapy using clinical outcomes. Measurement of clinical outcomes appears to be largely restricted to client populations enrolled in new disease management programs and is occurring on a limited basis. Several PBM clients noted that previous to the disease management programs, assessment of health indicators or clinical outcomes occurred sporadically when clients requested specific information about their patient population. Currently, these measurements are occurring more regularly within the defined disease management populations. At least one PBM is coordinating outcomes research efforts with its parent company, a major pharmaceutical manufacturer. Others are working in partnership with parent company subsidiaries which focus on disease management, information technology, or outcomes research.

PBMs are measuring a variety of outcomes measures, most of which are centered on "intermediate" patient outcomes, that is, laboratory results. Examples of these types of end-points applied to disease management populations include:

--blood glucose (diabetes program)
--glycosylated hemoglobin (diabetes program)
--blood pressure readings (submitted by physicians for hypertension program)
--peak flow meter readings (submitted by patients in asthma program)
--H Pylori testing (to identify patients eligible for peptic ulcer program)

Some PBMs are tracking emergency room, hospitalization and /or physician office visits as part of their new disease management programs, whereas others report that their clients perform these activities. One PBM only tracks emergency room visits and hospitalizations in the aggregate ("qualitative measurement").

Outcomes measures are submitted by the PBM to its clients monthly or quarterly. Data analyses are ongoing and generally are reported to the clients at quarterly intervals.

Quality of life assessments/Lost productivity

Several PBMs apply the SF-36 or SF-12 questionnaires to patients in disease management programs. PBMs also use disease-specific quality-of-life-surveys. These quality-of-life instruments are administered at variable intervals: quarterly once every 6 months, annually, or at 3,6,9 and 12 months.

One PBM reported that it assesses patient work loss to derive information on the indirect costs of lost productivity. Measurement of this parameter occurs though patient self report: patients are questioned about sick days and decreased on-the-job productivity directly related to his or her medical condition. This type of information is especially important to employers, who are at risk for the costs of lost productivity.

Quality of care assessments: HEDIS

PBMs are aware that HEDIS and other quality-of-care measurements are becoming more sophisticated, and in the future, PBMs may be called on by clients to respond to HEDIS measurements. This is already occurring to a limited extent. For example, one PBM's clients have become interested in whether the diabetes disease management program is decreasing retinal examinations and emergency room visits, two HEDIS indicators.

Satisfaction measures

PBMs conduct patient satisfaction surveys for those patients enrolled in a disease management program, using written surveys or verbal questioning by disease management case managers. Two PBMs surveyed physicians about the usefulness of its disease management program materials. Some PBMs conduct satisfaction surveys within the general population of PBM covered lives, but often PBMs reported that patient satisfaction surveys were in their clients' domain, but that they would conduct surveys at the client's specific request. One PBM mentioned that it monitored members' complaints as a way of staying abreast of the quality of its services. Finally, several PBMs noted an increase in the prevalence of clients demanding service guarantees in the area of members' satisfaction with various dimensions of care.

Impact of disease management programs

PBMs stated their intention to examine the clinical, economic and "humanistic" (quality-of-life) outcomes of their disease management initiatives, but in most cases the disease management programs have not been implemented long enough to evaluate these outcomes. Although PBMs are developing internal capabilities to conduct outcomes and cost-effectiveness analyses, there is also a trend toward collaboration with other research

partners. Specifically, PBMs are increasingly likely to collaborate with universities: one PBM is working in collaboration with a university to evaluate the outcomes of several of its disease management initiatives, while an employer coalition and insurer were doing likewise. Other research partners include pharmaceutical manufacturers and managed care organizations. These data are born out in a forthcoming paper surveying five leading PBM firms (Grabowski forthcoming, 1997).

In general, very few results are available. In a few cases, PBMs mentioned results of outcomes research on a specific disease which had been released publicly; in two cases, outcomes studied were slated to appear in forthcoming peer-reviewed literature. We were unable to review these data. As of this date, there are no disease management outcomes studies published in the peer-reviewed literature.

Barriers to implementation of disease management programs

A few PBMs are working with large clients (typically HMOs) to examine clinical outcomes, using data sets from the HMOs and the PBM. However, the integrated management of medical and pharmaceutical care through an electronic online network remains a major challenge to PBMs. As perceived by health plans, insurers and some PBMs, the main barriers to successful large-scale implementation of disease management programs are complex and numerous:

- difficulties in integrating medical and pharmacy data
  --medical claims data are not yet online or in real-time; (data may be old due to delays in claims processing);
  --medical claims data are used by some PBMs in their disease management programs but diagnostic codes can be problematic and laboratory data generally are nonexistent;
  --lack of standardization of medical data as there is in NCPDP standards ("NCPDP standardization is not there on the medical side") ("breaking medical data codes is challenging");
  --even when integration occurs, there are problems, i.e., medical claims data can be incorrect or vague, and the wrong inference can be drawn;
  --lack of capital to expend on merging pharmaceutical and medical data;
  --some health plans do not want to submit medical claims data to PBMs because they believe that physician and hospital reimbursement rates can be inferred from these data

- as noted in the discussion above, some employers are reluctant to purchase disease management programs from PBMs because they view such programs as being of untested efficacy. Other employers expressed skepticism about disease management programs, viewing them as efforts by PBMs to promote manufacturer's drug products to enhance rebate dollars; disease management programs sponsored by vertically integrated PBMs were especially subject to

this criticism (although some analysts argued that the breadth of the disease areas provided by these PBMs belies this point of view). One PBM advanced the view that employers did not "buy in" to disease management programs because they were not willing to give employees time off for educational and training programs necessary to fulfill program objectives.

- Ownership of the data: Some analysts expressed the view that the PBMs do not "own" pharmaceutical data; they process the data. These analysts maintain that the plan sponsors own the data: "We do not sell our data to anyone. We are not the sole owners of the information. The data belong to the MCO." Hence, if PBMs desire to mount disease management programs, they may be prevented from doing so by the plan sponsors. If plan sponsors do not permit sharing of the data with other entities or merging of different data sets, this could pose a barrier to implementation of disease management programs. Typically, the issue of data ownership is dealt with in the contract between the PBM and its client.

- lack of continuity of care results in lack of historical data: patients are moving in and out of health plans, and health plans are moving in and out of PBMs. As a result, PBMs' abilities to implement meaningful disease management is limited due to the absence, limited availability or lag time in obtaining historical data. For example, if a patient with asthma is targeted for disease management intervention, and if adequate history of prior drug use is unavailable, then there may not be enough information to perform a risk assessment to determine the patient's needs in terms of specific disease management support. Further, if data on previous hospitalizations or emergency department visits for an asthmatic patient are not available, it might not be possible to assess how well the patient's treatment is progressing and symptoms are controlled. The patient may need inhalers or counseling on the proper use of inhalers, but being able to determine this is very difficult without corroborating historical medical use information.

Given the absence or unreliability of diagnostic data, some PBMs infer diagnoses from drug data; however, drugs are not always valid markers of diagnoses. (For example, diabetes can be inferred reliably from the use of hypoglycemic agents, whereas the use of bronchodilator therapy can be indicative of asthma, chronic obstructive pulmonary disease, or other respiratory diseases.) In addition, some PBMs derive diagnoses from patient

self-assessment questionnaires distributed by PBMs to enrollees who volunteer to participate in their disease management programs; this method may not consistently yield valid results.

Future of disease management programs: The importance of computerized information systems

Several respondents observed that information systems are the key to the future viability of PBMs. Currently, most PBMs reported that they were using, or planned to use, computerized claims databases as data sources for outcomes research.

At present, there is information asymmetry between the PBM and the health plan. Some argue that this "disconnect" between the pharmaceutical and medical data bases makes the realization of disease management objectives problematic, i.e., who is accountable for the health of the enrolled population and for seeing that enrollees receive optimal health care when these responsibilities are divided? (This problem of coordination of care applies to all carved-out benefits.) PBMs counter that the so-called disconnect between pharmaceutical and medical data is no more problematic in PBMs than in group model HMOs (e.g., Kaiser) or in Medicaid programs -- organizations which historically have kept their drug and medical budgets totally separate. Medicaid analysts counter that their programs have the ability to link the two databases more easily. New "evidence-based" information must be provided to physicians to improve prescribing practices and the provision of other medical services. Some PBMs predict that they will become the central repositories of both medical and pharmaceutical data because they have the capital, drug use data bases, expertise, infrastructure and the ability to develop and implement the computerized information systems and the interventions that produce behavioral change among physicians.

Limitations of PBM-sponsored disease management programs

Several observers expressed the view that PBM-sponsored disease management programs are not oriented toward examining the whole patient. Many patients (especially Medicare beneficiaries) suffer from multiple chronic diseases. Critics of disease management programs contend that focusing on a single disease in such patients is a very narrow and fragmented approach. Ultimately, such disease management strategies will not serve the public health or the health plan's purse. For this specific reason, one PBM noted it is shifting its strategy from a single disease focus toward an overall patient management approach.

A recent Scott-Levin survey of 26 HMO pharmacy directors suggests dissatisfaction toward disease management programs sponsored by pharmaceutical manufacturers, largely due to concerns over conflict of interest (as reported in *Managed Pharmaceutical Report*. April 1996:7). In the current study, two managed care

organizations expressed similar concerns about disease management programs sponsored by vertically-integrated PBMs. How widespread these views are, and how much veracity there is in their concerns, are questions in need of systematic investigation. Disease management programs are being developed by medical groups and integrated delivery systems. Given some clients' concerns about objectivity, it is possible that disease management programs may be more likely to be adopted in such settings.

Cost Savings in a PBM Environment

A major goal of PBMs is to achieve cost savings for their clients while maintaining or improving quality. Interview questions were designed to obtain information from PBMs about cost savings. Specific questions were included to gather information in the following areas:

1. PBMs' pharmacy payment formulas (drug cost and dispensing fees) to compare with existing Medicaid payment rates.

2. Actual cost experiences via per-member-per-month (PMPM) cost (expenditures) for a marketbasket of drug categories.

3. Trends in overall PMPM costs for the PBMs.

4. Rebates obtained from pharmaceutical manufacturers.

5. PBM cost savings, to what savings are attributed, and the success of various efforts to control costs.

The information obtained on these areas of PBM activity was used to estimate cost savings and cost impacts that PBMs have achieved for their clients, and the potential for savings relative to existing Medicaid programs. PBMs answered questions in these areas with varying degrees of specificity, and in some cases, not at all. Data from the interviews for each of these areas of inquiry about cost are summarized below.

1. Pharmacy Payment/Reimbursement

A summary of pharmacy payment parameters reported in the PBM interviews is summarized in Table V.9. The table includes "typical" or "usual" payment formulas reported by the PBMs. Since PBMs represent large numbers of covered lives and corresponding large prescription volumes, they have been aggressive with their payment terms to pharmacists for prescriptions, often establishing the deepest discounts in drug cost reimbursements and dispensing fees. A comparison with State Medicaid payment

formulas shows they typically have had higher discounts off AWP for ingredient cost reimbursement and lower dispensing fees.

Table V.9
Summary Of Pharmacy Payment/Reimbursement Parameters

PBM	Ingredient cost	Dispensing Fee	U&C[1]	MAC & Comparison[2]	How Set MACs?
•	AWP - 13% or 15% (chains) AWP - 13% (independents)	$2.75 $2.75/3.50 brand/generic	Yes	Yes, > State mini-MAC	600+ drugs, updated monthly
•	AWP - 10% AWP - 13% depends on network	$3.50 (or $3.00) $2.50 (or $3.00) ($2.25-$4.00 range)	Yes	Yes, > State mini-MAC	Adjusted for generic availability and market information on costs, continuously monitored
•	AWP - 10% (Medicaid) AWP - 10% (Commercial)	$3.00 $3.00	Yes	Yes, > HCFA MAC	Own MAC list
•	AWP - 10% or 13%	$3.40 (average across states) $3.00 or $2.50 depending on network	Yes	Yes, prices average 68% less than AWP for corresponding brand-name drugs	Availability and marketing information reviewed quarterly, continuously monitored and adjusted
•	AWP - 12% (norm) AWP - 14 or 15% (others)	$2.50 $1.95 or $2.00	Yes	Yes, > HCFA MAC	Take out hi/lo and average rest of generic products
•	AWP - 13%	$2.50	Yes	Yes, > State mini-MAC	HCFA MACs, competitors' MACs, AAC audits
•	AWP - 10/15% (brand/generic) AWP - 13/20% (br/gen) deep discount network	$2.00/3.00 brand/generic $2.50/3.50 brand/generic	Yes	Yes, > HCFA MAC	Avg. AWP or AWP - 50% for managed care
M.A.[3] norm	AWP - 10% (24 states at AWP-10 or 10.5%, only 2 states with > 10.5% off)	$4.12 (avg. of all dispensing fees - based on lowest fee if range paid)	Yes	Yes, usually HCFA MACs, but many states have additional drugs on their mini-MAC lists	via HCFA policies, or adaptations thereof

[1] U & C refers to whether the PBM has a "lower of" Usual and Customary price clause, where payment is based on the PBM payment formula or the pharmacy's usual and customary price, whichever is lower.

[2] Note: The MAC comparison is difficult to assess completely. Most PBMs reported using HCFA or State MACs as a component in considering/developing their own MACs and they went beyond these already established limits, both in terms of numbers of products covered by the MACs and in reducing the amounts allowable for payment.

[3] M.A. = Medical Assistance (Medicaid).

In general, PBMs follow the reimbursement mechanisms established in State Medicaid programs. All include a provision that the pharmacy may charge the PBM no more than the lower of the pharmacy's usual and customary charge (price charged to a cash paying customer) or the amount established by the PBM reimbursement formula. For multi-source (generically available) drugs, PBMs, like Medicaid, have Maximum Allowable Cost (MAC) programs.[22]

Most PBMs reported their MAC programs were more aggressive than Medicaid MACs, especially relative to the HCFA MACs (FFP upper limits). We did not obtain specific listings of MAC drugs and MAC amounts, thus a direct comparison with State "mini-MAC" programs was not possible.[23] However, it is likely that PBMs have at least equivalent MAC programs compared to the states, because state MACs are readily available to PBMs as a guide or baseline for establishing the PBM MAC lists and MAC prices. Most PBMs also reported moving quickly to establish MACs when patents expire and generic versions of commonly used brand name drugs enter the market. They also noted close monitoring of prices for generic drug products via monthly review, whereas HCFA MACs are published only twice a year.

Several PBMs made additional comments about the pharmacy payment levels, how they establish them as market rates based on the competitive strategies pharmacies use, and their effects. Their remarks include:

> *"Bidding stems from pharmacy chains -- we know what they can deliver, and we go directly to the [chain] pharmacy and make an offer."*
>
> *"It is possible to get reimbursement down to AWP - 17 percent in custom networks."*
>
> *"Pharmacies know the contracts game. Caution -- you can get less value out of a contract for AWP - 15 percent versus AWP - 13 percent because some pharmacies won't be delivering on their promises. Some chains won't give you great value, but you have to decide if you need them anyway for access."*

---

[22] Maximum Allowable Cost (MAC) is the upper limit amount that will be paid for the ingredient cost portion of a dispensed prescription for a multisource (generically available) drug. The MAC is set to estimate the cost to pharmacists for generic versions of a drug, and that amount is paid regardless of which firm=s product is dispensed. Thus, MAC pricing fosters the dispensing of generic drugs. The Federal HCFA MACs often are referred to as "Federal Financial Participation Upper Limits" (FFP upper limits) since HCFA sets aggregate upper limits for drug payments across drug products for a variety of drugs and will withhold Federal funds from states whose drug costs exceed the uper limits.

[23] States often revise the HCFA MACs by adding drugs and/or revising the payment levels to match acquisition costs more accurately on the state level; these adjusted MAC lists often are referred to as State mini MACs.

A PBM consultant noted HCFA MACs are the starting point for establishing their MAC programs, both in terms of the products included in the MAC program, and the payment amounts. PBMs make modifications up or down because HCFA MACs are not updated frequently enough and do not cover all drugs. These comments reflect the aggressive pricing strategies adopted by PBMs for pharmacy reimbursement.

2. Costs for Drugs/Marketbasket of Drugs

The *Ciba Pharmacy Benefit Report - HMO Facts and Figures* (1994) of PBMs includes data on cost PMPM for drugs in therapeutic categories. Since PBMs provided these data for this report, similar information was sought to contrast different PBMs, as well as PBMs and Medicaid. PBMs were asked to provide PMPM costs, average prescription size and days supply for a marketbasket of 8 drug groups (see Appendix A).

Most PBMs did not disclose this information. It appears that these data are considered proprietary or may not be readily retrievable. It is possible that these data are not part of standardized reports or monitoring information used by the PBMs.

Only one PBM completed a cost matrix of PMPM costs for the marketbasket drugs in the survey protocol. The costs it reported were based on AWP and pointed out that differences in patient groups and plan structure affect costs. The PMPM varied across targeted subpopulations for which the reports were generated (managed care, Medicaid "at risk" group, commercial book of business). Variances in AWP PMPM amounts were related to average prescription sizes, days supply, etc. that varied across groups because of differences in plan benefit structures, patient mixes, and drug utilization patterns in the various subgroups.

This market comparison did not prove useful, not only because of poor response rate, but also because of variation in the patient and drug use mixes generating the aggregate results. This kind of comparison potentially could be useful, particularly for clients to monitor program changes and cost trends in specific drug categories, or for prospective clients to compare their existing cost experiences with a similar, matched cohort of PBM clients. In such instances, PBMs likely would divulge such data.

3. Changes in Costs PMPM

The PBM executives and staff interviewed were very forthcoming in sharing their aggregate experiences in changes in costs PMPM and trends over the past several years. PBMs were asked about prior trends, current experience, their expectations for the future, and to what factors they attribute the changes.

Changes in PMPM cost experienced by some PBMs in recent years were in the range of 6 to 8 percent increases. However, other PBM executives predicted more possibly double digit increases likely will be seen in the future relative to savings or flatter trends that have occurred previously. They remarked that the "easy costs have been squeezed out," referring to downward pressure on dispensing fees and decreased ingredient cost payments through larger percent discounts off of AWP, and shifts to more generic dispensing. Additional reimbursement formula savings resulting from exclusive provider arrangements or restricted panels may be difficult given any willing provider legislation in many states and an increasing unwillingness of pharmacist providers to take additional decreases in reimbursement.

Other drug use management efforts to reduce costs may be more difficult for PBMs to initiate and/or control via centralized administrative and policy efforts. These other efforts, such as restrictive formularies, aggressive therapeutic interchange and prior authorization, disease management, etc. require involvement and additional efforts primarily by PBMs and provider pharmacists, but also by physicians, patients, and PBM clients.

The PBMs attributed current cost trends to changes in the mix of drugs dispensed, increased utilization, and shifting of some drugs such as injectibles to the drug benefit from major medical coverage. Trends in cost changes are reflected in the respondents' remarks summarized in Table V.10 below. Some caution is needed when interpreting the reported figures. The trends are aggregate and encompass many concurrent and potentially countervailing changes that have been occurring such as benefit structure changes, client shifts and aggressiveness of clients with drug benefits and design, changed reimbursements, and clinical programs. It is not clear whether PBMs or their clients can assess and attribute PMPM changes accurately.

Comments from PBM clients provide additional insights because they reflect experience from the buyer's side rather than what the sellers (PBMs) want to reveal. Their comments suggest costs increases because of several factors, including drug cost inflation, new drugs being introduced at premium prices, changed patient incentives in service benefit versus indemnity benefit programs, adverse selection, and inadequate monitoring of PBMs. A few believed that hiring pharmacists to monitor and enhance PBM efforts and enable more aggressive application of PBM cost and drug use control techniques is an effective cost containment strategy. Selected comments are as follows:

> *"In my three-year history with this health plan, we had increasing PMPM costs every year, until we hired our own clinical pharmacist. In 1993, we had a 22 percent increase in drug costs and in 1994, an 11 percent increase. Then, the health plan hired its own clinical pharmacist, and in 1995, PMPM was flat, and in the areas we've examined, we documented improvements in medical costs. To obtain this slow-down in PMPM increases, we added a few more drugs to prior authorization, stepped up physician education about the formulary, improved the formulary, tracked high-cost drugs and developed patient-friendly guidelines*

about lower cost-prescription drugs, and developed clinical guidelines. We did not change a thing in our contract with our PBM."

"We have seen an increase in PMPM. Why? Due to changes in our benefit design and increased utilization. In 1993, we had a paper claim benefit with our PBM. Our shoebox effect wasn't that big, but utilization increased when we shifted to an electronic card program and a cost-share for drugs; it reduced a barrier to filling scripts for beneficiaries."

Table V.10
Summary of PBM Responses About Changes in Cost PMPM[1]

PBM	Prior Trends in PMPM	Current PMPM Trend	PMPM Changes in Future	Causes/Comments
•	drug cost decreased prior to 1994	6-8 percent increase in the last few years	double digits for 1996	Federal Health Care Reform failure, inflation, fewer drugs off patent, increased self administration of. injectible drugs versus in major medical
•	7.5-3.7 percent consistently decreasing 1991-94, 1.5 percent mix increase 1993-94	3.5 percent due to price (inflation), 2.2 percent due to product mix changes		
•	increasing, but at a decreasing rate	6-10 percent increase currently		lower increase rates due to manufactures being forced to keep price increases under CPI
•		6-8 percent increase last year		increased utilization and costs (price inflation)
•	for some clients, PMPM costs decreased by 30 percent			
•	10-13% increase in past 2 years		lower increases for those with more controls	increased utilization, increased prices, more expensive therapies
•	price (inflation) fluctuated between 4-6%; utilization varied by client	price (inflation) trends between 2-4%; utilization trends between 2-5%	price trend increases will flatten, but still rise at a rate of 3-4%	increasing focus on controlling PMPM cost versus a rebate emphasis; significant impact of brands coming off patent to generic, offset by new potentially higher-cost therapies

[1] Since the survey questions were open ended, a variety of responses resulted. An attempt to categorize them into prior and current trends and projections was made for developing this table, but not all responses fit this categorization easily.

"Other factors for increases in PMPM? First, as a primarily fee-for-service insurer, we are retaining the higher utilizers (drug and medical) as HMO plans are attracting younger and healthier patients. Second, on the retail side, rebates are much smaller than those available to institutions."

"PMPM costs cannot go down. New, expensive drugs are always coming out. But inflation is slower than it otherwise would be without a PBM. You have to be careful. You don't want to hold down costs on drugs because medical costs might go up. Our firm is integrating pharmacy and medical data to monitor overall health services utilization. The studies we did with Imitrex showed that we got 80 percent fewer ER visits but spent 10 times as much on the drug as we would have on ER costs. We then would need to look at quality of life and indirect cost measurements such as, were there fewer sick days, and how much money did we save the employer in avoiding lost productivity? We haven't been able to measure these elements yet."

"PMPM costs were increasing rapidly due to: (1) inadequate monitoring of PBM activities; and (2) drug cost inflation. Costs were brought in line only after the health plan hired a pharmacist to oversee the plan's needs."

The theme of these comments is that savvy PBM clients will work in close collaboration with their PBM vendor. Some clients hire pharmacists to add in-house expertise in assessing programs and better select or target programs for their specific needs.

One health benefit consultant observed PMPM drug costs were increasing at a slower rate, due largely to changes in benefit structure rather than aggressive clinical management of drug prescribing and use:

"The 6 to 8 percent increases seem too low. PBM plans have undergone a host of benefit changes (added prior authorization drugs, dropped drugs from formularies, etc.) which have depressed PMPM increases, but the slowing of the increases have not been attributable to aggressive clinical management of drug use. But, while the rate of growth is less than it used to be, drug costs are still going up -- how can they not, with new, expensive drugs coming into the market all the time. A 6 to 8 percent increase may be accurate for PBM "X" (name withheld) because their client niche is HMOs, which have their own Pharmacy and Therapeutic committees that are aggressive on the clinical side, and HMO patients are used to restricted choices. They also have the best rebates in the business, which might help account for slower increases in PMPM."

"Neither employers nor PBMs themselves delve into the causes of PMPM increases. Sometimes it's not the PBM's fault. For example, employers

implement a flat dollar co-payment which leads to an unintended benefit improvement due to inflation."

"But, PBMs are over simplifying things in their client reports. They don't look at the sources of change within their population, e.g., aging. There are decreases in PMPM that result from new generics or drugs going off patent. But if you don't look at the component pieces, if you don't identify the causes of change, you don't know what are the drivers of change -- you can't manipulate your own 'machinery' --you don't know how to achieve your goals or avoid your problems."

Overall, both PBMs and clients realized multiple factors were influencing their PMPM costs and will continue to influence future changes. There also was a sentiment that successful clients had more involvement and savvy managing their drug benefit. A consultant's comment sums up the responses about PMPM trends and influencing them:

"The differences in employers' experiences with the PMPM costs is due in large part to their level of aggressiveness with their drug benefit."

4. Contracts/Rebates

For many, rebates are perhaps the most provocative and controversial aspect of PBMs. Many of the complexities of PBMs, ranging from all aspects of drug use management (formularies, prior authorization, differential co-payments and dispensing fees, etc.) to charges between clients and PBMs somehow can be related to rebates. They also are of legal interest to pharmacists due to discriminatory pricing issues, and pharmaceutical manufacturers because of concerns about anti-competitive behaviors of manufacturer-owned PBMs. Consequently, they were a delicate subject in our interviews with PBMs and their clients and generated interesting observations.

Several PBMs quantified the amount of rebates they earned per claim and as a percent of "total drug spending," defined as the PBM reimbursements -- drug cost plus fee less applicable co-payment. These amounts varied among different clients/plans. Clients with aggressive drug use management programs, such as managed or closed formularies, could achieve higher rebates because the rebate levels now often are linked to market share changes.[24]

[24] Note that change in market share is now the focus of most rebates, rather than volume. Increased volume can be a side effect of increased enrollments and business growth, but increased market share within a therapeutic class or drug category reflects changes in the use of competing products relative to each other.

This linkage between influencing market share and rebate level is a critical aspect of rebate programs. It also may be one characte istic where PBMs may differ from Medicaid programs; their ability to direct drug usage via formularies or other drug use management efforts, including patient financial incentives, may be more developed and successful or applicable than most Medicaid programs where relatively open access to all pharmaceuticals is the norm. Several PBMs maintained that "rebate myopia" can be problematic. The real issue lies in net ingredient cost in programs, the average within a therapeutic class. Bona fide drug use management techniques may be better at influencing overall costs, both within the drug budget and total health care costs, than rebates or discounts on drugs used indiscriminately.

A summary of quantitative responses to questions about rebates is shown in Table V.11 below. The responses are de-identified and scrambled to protect PBM confidentiality. On a per claim basis, an overall estimate of rebate falls around $1.25 for the PBMs that shared information with us. Typical nominal amounts ranged between $1.00 and $1.50; reported specific plans ranged from $0.80 to as high as $2.50 (admittedly an exceptional case). As a percent of total drug spending, respondents' estimates hovered around 6 percent, again with variability across PBM and plans/clients within PBMs.

A few PBMs also quantified approximate percent rebate levels, nominally and/or relative to OBRA '90 Medicaid rebates. These responses included "13 to 15 percent on rebatable drugs," "9 to 10 percent rebates on brands," "10 percent is a good rebate -- 17 percent on some products," "much lower than Medicaid," and "about 90 percent of what Medicaid gets." They also noted they had less ability to extract rebates universally from manufacturers they deal with, especially generic firms, unlike what Medicaid agencies have accomplished via OBRA '90. One PBM noted that, "If a product of a manufacturer is excluded, then you will lose rebates on the rest of the product line."

The above estimates need to be used carefully. They are based on self-reported figures from a limited number of responding PBMs. Assuming that these responses are valid and representative, the figures give a rough estimate of the magnitude of rebates achieved by PBMs.

The following are selected interview comments about rebates. They reveal some curious conflicts in PBMs' experiences and descriptions of rebates.

PBM Comments

"Rebates are decreasing. The terms are decreasing (1 yr. versus 2 yr. previously). Twelve companies dominate the rebate market (80 percent of rebates). Rebates used in pricing -- clients expect it."

"Rebate terms are decreasing. They have a contract with a "rebate management" firm that does the negotiating/contracting with manufacturers. The market share

driven aspects of rebates is becoming a critical factor."

"Medicaid gets generic rebates and we don't. Medicaid rebates are fair, but they're not moving market share. All growth in rebates is market share driven. Rebates start at a base, aggressive discount (due to PBM size/market share), then market share incentives kick in; 98 percent of firms have rebates based on market share."

"Rebate terms are increasing (1 year. was previous norm, now 2 years). 75 percent of rebates is based on volume, 25 percent on market share. 50 percent of rebate dollars is based on performance, 50 percent are base rebates. It is not common for a product line to be discounted/rebated as a bundle."

"Medicaid gets a warped drug mix. It's the ingredient cost that's much more important to costs than rebates. Rebates are not where the value is... therapeutic switch is where you get value -- with antibiotics, the rebate would look minimal because we want to move more utilization to generics. The old question for clients was: how much rebate? -- the new question is: what is the lowest PMPM for a therapeutic class? -- getting lowest per claim cost in each class gives best value... this concept now is driving the industry."

"We are not getting the OBRA '90 rebates. Rebates don't do anyone any good since they are given by brand name products to drive market share. Under capitation, the less you sell, the lower the cost per unit, the better the business you are going to run. We are trying to maximize generic utilization. Rebate-driven PBMs go after the higher cost, brand name drug because of the larger rebate amounts; however, this increases the costs to clients. In selected cases, the brand name may cost less as a result of the rebate. Increased competition has led to increasing rebate percentages in all market sectors."

Comments from Other Interviewees

"Most national accounts have open formularies. PBM "X's" (name withheld) are going way down because manufacturers know they have not been able to move market share with an open formulary."

"Rebates are decreasing, but we have a handle on our share. We're big, so we can command a substantial share of rebate dollars. The PBM takes a fee for managing the rebate activity."

The experience of HCFA rebates for state Medicaid programs serve as a comparison for the rebate information obtained from PBMs. A report of the initial experience of the Medicaid rebate program showed rebates as a percents of fiscal year Medicaid drug spending increasing from 4.6 percent in 1991 (the first year of the rebates)

to 13.0 percent in 1992 and 17.0 percent in 1993 (U.S. Department of Health and Human Services 1995). Current Medicaid experience with rebates was assessed by analyzing HCFA rebate data for third quarter fiscal year 1995 (1 April to 30 June 1995). The total dollars of rebates earned for each state were used to calculate the percent of drug spending that is rebated. This analysis showed rebates equal to 18 percent to 21 percent of drug spending across state Medicaid programs. These data, particularly the most recent calculations, support the PBM assertions that they are unable to achieve the same level of rebates as Medicaid. Confirming the assertions is beyond the scope of this present study, especially given the complexity with how rebate arrangements are structured between PBMs, manufacturers, and clients.

There are imitations in comparing the HCFA rebates with PBM experiences. First, the mix of products dispensed likely differ across PBMs and Medicaid programs because the populations covered are different. Second, drug spending, although consistent in definition between the two groups (net expenditures for prescription payments), incorporates varying pharmacy payment formulas for drug cost and dispensing fees and differing co-payments across PBMs and Medicaid programs. This results in different denominators for calculating rebate amounts as percents of drug spending. Third, it also is possible that the rebate may be based on different amounts within the PBM industry compared to Medicaid programs. For Medicaid, rebates are based on Average Manufacturer Price (AMP), whereas PBM rebates may be based on amounts relative to their programs, such as drug payment formula amounts (discounted AWPs or MACs). Such limitations need to be considered before generalizing about or comparing the rebate information included in this report.

A difficulty in interpreting and computing rebates is having a consistent "denominator" to assess rebate level. Rebates expressed as a percent of expenditures brings confounding factors of drug reimbursement and patient cost share differences, plus mixes between retail and mail distribution channels, with attendant variances in days supply, product mix, and percent of prescriptions dispensed through each channel. Rebates based on the cost of drugs might be derived from Average Manufacturer Prices (AMPs) as in the Medicaid program, or AWPs as "standardized" price references, including originators' AWPs or redistributors' AWPs that potentially are inflated to advance the purposes of those using the numbers. Broad conclusions about comparative rebates are made at an author's peril.

Some PBMs described how rebates they negotiate are passed on to clients. They may use rebates as part of their pricing/marketing strategies, in part because clients expect it. The rebate arrangements with clients are structured to "share" the rebate that PBMs negotiate with manufacturers, turning most of the rebate (the total less an "administrative" proportion) to the client. Interviews with clients revealed that there is considerable variability in the percent of rebate shared, ranging from 0 to 100 percent of rebate earned by the PBM.

Comments from some respondents suggest other contracts exist between PBMs

and manufacturers that may be different than, but at the same time, similar to rebates. Arrangements may be present between PBMs and manufacturers to share drug use information (in addition to that needed for rebate calculations) or for other information or project-based effort by PBMs. These arrangements in the form of "incentives to the PBM for the production of information" or "funds from projects sponsored by the manufacturer," may be structured as percents of drug costs, as are rebates, or as fees as a flat amount or per claim amount.

These notions were reinforced by comments from a PBM consultant:

"Rebates to the PBM can be visualized as falling into 2 "pots." Pot A contains the rebate dollars which the PBM reports (and returns a portion of) to its clients. Pot B contains other money which can be called "rebates" which the PBM receives from the manufacturers. PBM clients receive zero percent of these funds. These funds may be overall rebates which the PBM attributes to "its entire book of business" -- a problematic way of thinking, because by definition the book of business made up of plan sponsors! Or, the funds may come in the form of "incentives to the PBM for the production of information" or "funds for projects sponsored by the manufacturer." I think of these funds as "rebates" because I bet if the PBM wasn't getting funds under these categories, the amount of "technical" rebate dollars would be higher. But the transfer of funds under the Pot B categories is in the best interest of the PBM's pocketbook because it gets to keep the money!"

Table V.11
Summary of Rebate Question Responses -- PBMs Providing Quantitative Responses

PBM	Rebate/Claim	% of Drug Spending	"Levels" of Rebate	% of Brand Prods with Rebates	# firms giving Rebates	Structure of Rebates
•	$0.80	3-5% of dollars	"much lower than Medicaid;" 13-15% of rebatable drug costs		multi-source only if the PBM can get high level market share	
•	$1.20-1.80 typical, cab be as high as $2.50	2-6% of dollars for plans with formulary	10% good, 17% on some	for rebates on formulary drugs ~ 30% of a plan sponsor's RXs	"all they deal with" = 40+ manufacturers	20-30% administrative fee to PBM
•	$1.00-1.25	5-9% of total claim dollars	about 90% of what Medicaid gets for brand rebates	80% of rebates are on brands	50+ firms	90% back to client; administrative fee negotiated, 30% of plans at 92% return to client
•	$1.44 overall average; with no network & voluntary formulary = $0.94; network & closed formulary = $1.51	6.4% of drug spending for HMOs	9-10% on brand	60% of brand products	~50	"shared," admin. charge and rebate, or "entire" rebate to client
•		4-5% of drug spending				rebates are returned to the client; the PBM receives a small portion of the rebates

5. Cost Savings Estimates

The interviews probed PBMs about cost savings generated. Limited "quantifiable" data were reported in this section of the survey questionnaire and thus, "standardized" cost savings estimates can not be derived readily. One PBM consultant respondent expressed it best: "It is all imputed, a gray science. There are so many variables, and we do not have all the data we need." Another respondent noted, "Some PBMs say that they have saved the client money, but they are factoring in drugs coming off patent -- savings that would have accrued to the client without the PBM."

Potential savings a PBM might offer vary considerably based on what the client's baseline for comparison is. For example, if a PBM is taking on a client that formerly had an indemnity prescription coverage plan, savings would be different and derived from different areas than if a new client was a managed care organization or a former client of a competitor PBM who had instituted some drug use and pharmacist payment control measures.

Savings can result from reduced pharmacist payment levels, changed patient incentives in the form of increased co-payments or co-insurance rates, formularies, or other drug use management programs. Parameters that may be relevant, depending on the change(s) associated with the PBM might include "shoe box" effects[25], moral hazard, cost sharing price effects, product mix variations, access to pharmacies or specific drugs, etc.

PBMs reported using historical comparisons for evaluating changes/savings, typically using the onset of a contract as a client baseline, but also incorporating comparisons with previous clients or the entire PBM business as a benchmark. Most PBMs have the capability to match clients in several ways (demographics, drug use patterns, client type, "insurance" type -- MCO versus indemnity, etc.). They can report PMPM costs, utilization patterns, generic/brand trends, etc. The most valuable assessments of savings result when it is possible to "decompose" the expenditure changes (savings) and attribute them to different efforts or drug management programs (e.g., concurrent and/or retrospective DUR, benefit designs and cost sharing, network rates and incentive programs, formulary compliance, generic savings, rebate program performance, disease management programs, etc.). One PBM client reported "the PBMs report cost savings to us based on the interventions applied, and our actuaries monitor their calculations." However strict isolation of the effects of different component programs may be difficult to achieve (especially in operational programs without the ability for controls). Decomposing expenditure changes probably would show changes in both

[25] The "shoe box" effect refers to indemnity benefit programs where beneficiaries will accumulate receipts over a period of time (sometimes in an old shoe box) planning to submit them at year-end or when their deductible is exceeded, but forget or omit some amounts. When these beneficiaries are converted to a service benefit program (the typical PBM method), claims are submitted by providers when they occur, and thus no claims are shoe boxed, thereby increasing costs to the insurer/payer.

directions, increases and decreases, because different efforts or aspects of the benefit management would have different effects.

One PBM offered projected incremental savings for clinical management programs of 3 to 8 percent, closed formularies of 4 to 8 percent, and prospective DUR of 2-4 percent, although they acknowledged that the DUR estimate might not be true savings because it is measured by calculating rejected claims and because P-DUR now is a standard "given" in claims processing functions. Another PBM estimated 4.5 percent savings resulting from prospective DUR. Other comments included a report of 15 to 20 percent savings over major medical reimbursement, and an estimated 10 to 15 percent "shoebox" effect that the PBM will go at risk for, given that formularies, volume, network, and increased generic use can compensate for the shoebox effect. An insightful client remark was "PBMs create competition within therapeutic classes, a cost-containment strategy our MCO has been using for years. PBMs have brought this strategy to the indemnity market."

Additional Perspectives: Clients and Benefits Consultants

Understanding clients' perspectives is critically important because their views regarding the value of PBMs and their strategies to control costs and improve quality have a major impact on the PBM industry. To obtain insights into the perspectives of PBM clients (also called "plan sponsors"), a total of six managed care organizations/insurers and four employers/employer coalitions were interviewed.

Description of PBM clients

Eight of the ten PBM clients had one contract with a PBM. One MCO with multiple contracts had one contract for the overwhelming majority of its clients except one that had an "historic relationship" with another PBM. The other multiple PBM client, an insurer, had contracts with two PBMs, one to provide mail service and the other to serve as claims processor, network manager, and rebate negotiator.

At the time of the interviews in March, April, and May, 1996, clients' PBM contracts had been in operation from four months to eight years. The number of covered lives included under these contracts ranged from 50,000 to 3.5 million.

Clients contract with PBMs via pharmacy benefit carve-out arrangements for several reasons. Chief among these is the cost efficiencies inherent in using PBMs' computer system for claims processing and adjudication:

> *"We needed a PBM because there was no possibility that we could establish our own computer system less expensively than using a PBM,*

which already had a sophisticated computer system in place. It's really a matter of cost. The rates that the PBM have given us are so low -- we couldn't come close to these rates wer we to do it in-house. "

Clients also rely on PBMs' computerized systems to generate periodic reports on drug utilization and expenditures which enable them to implement incentive programs for patients and pharmacists.

Most clients chose PBMs because of their clout with drug manufacturers in negotiating rebates and other discounts. In one instance, a client chose a particular PBM because it allowed the client to establish its own formulary and distributed rebate dollars based on market share on a client-by-client basis. In a sense, the PBM permits a client to receive "credit" for shifts in market share based on the use of its own formulary. The client stated that other PBMs distribute rebates to clients on the basis of market share calculated as an average of the PBM's national book of business.

While many self-insured large employers contract with PBMs, not all employers are interested in full-service PBM contracts. One self-insured employer does not use a PBM to manage the pharmacy benefit because, "About 80 percent of our employees are in HMOs now, and we do not have to worry about their drug benefit." Further, drugs used commonly by the 20 percent of employees remaining in fee-for-service are largely for acute conditions not lending themselves to mail order service, and employees considered mail order "inconvenient." This employer only wants the discounts that a PBM network could offer. As a result, it "rents" a PBM's pharmacy network so as to gain access to discounts via reduced reimbursement to pharmacists. According to the employer, these discounts have proved successful: they have eased the financial burden for the company and its employees, especially those on expensive maintenance medications such as immunosuppressants and other chronic drugs.

Terms of PBM contract regarding payment for PBM services

Clients' payment arrangements to PBMs vary by contract. As noted by one PBM spokesperson: "If you've seen one contract, you've seen one contract." Most PBMs are paid on a "per claim" basis. Typically, this "base rate" does not include clinical services such as disease management, prior authorization, and pharmacist formulary compliance incentive programs. However, in a couple of instances, clients pay a "per claim" fee that includes clinical services, while others pay an "up-front global fee" which covers claims processing and adjudication, online DUR, and periodic reporting.

Only one surveyed PBM client, a managed care organization, put its PBM at risk through sub-capitation. The MCO has a state contract to enroll Medicaid patients. Its PBM is paid "PMPM" (per member, per month); both claims processing and clinical services are included in these monthly payments. This client believes that having access to the state's historical and paid claims data permits derivation of an appropriate capitation

rate, whereas other clients try to ensure PBM accountability through other risk-sharing arrangements such as savings guarantees and performance standards.

Most clients are unwilling to capitate PBMs, largely because they believe that capitation would result in loss of patient choice and employer control over major decisions and information flow:

> *"We are not capitated because we want to preserve our company as an individual choice market. We want control of communications, interventions, and treatment of members. We want to continue to deliver on our promises to members; as a result, we do not want to forfeit some of our rights of control for a capitation contract."*

Some clients asserted that capitating PBMs could result in greater overall medical costs. If PBMs were capitated, it would encourage them to use the lowest-cost drugs to come in under the capitation rate, potentially resulting in higher overall medical care expenditures.

While PBM clients may not choose to capitate the PBMs, they are increasingly demanding that other risk-sharing arrangements be established. Chief among these are savings guarantees for multiple PBM functions and financial penalties of performance standards are not achieved:

> *"If the PBM guarantees a savings of 2 percent, and if we see that the 2 percent is achieved, we will share it with the PBM."*

> *"We have a 'dollar-for-dollar guarantee' with the PBM: if the PBM does not meet a savings guarantee specified in its contract, then it gives us money up to the amount of the guarantee."*

> *"The PBM pays a penalty if it fails to meet a performance standard (e.g., guaranteed minimum waiting times for member services telephone lines, meeting a targeted generic utilization rate, etc.)."*

Churning in the PBM market: reasons for PBM switches

Three of the five MCOs had switched PBMs, and one was actively considering a switch. Multiple reasons were offered for these changes. In some cases, PBMs were not performing certain clinical functions optimally or at all; in other instances, clinical functions performed by a PBM were not perceived by clients to be "state of the science" (e.g., DUR was not on-line, real time). Further, clients switched PBMs because in their view rebate decisions were too secretive and it appeared that formulary decisions were based on rebates rather than on clinical information. (This concern was more likely to be expressed with regard to vertically integrated PBMs.) Finally, several plan sponsors --

especially self-insured employers and insurers operating in the large group market -- observed that health benefits consultants contributed to firms changing PBMs: typically, when contracts have expired, consultants are hired to re-negotiate new contracts. Health consultants generally recommend that an RFP [request for proposal] process be used, on the assumption that competition among PBMs will result in lower costs for the employer. In contrast, it was reported that "churning" was less prevalent in the small-employer group market. In this market, the employers receive whatever the insurance carrier offers. There are no negotiations: it is "one-stop shopping."

Some plan sponsors stated that PBMs have not affected prescribing patterns or shifted market share in large part due to the nature of the customer base and their generous drug benefit plans. For example, some large employers and unions are unwilling to restrict the formulary or establish preferred provider networks because they fear employee discontent with limited choice of drug or pharmacy. Hence, plan sponsors are considering other PBMs in an effort to achieve cost savings in the face of these constraints:

> *"When we select a PBM based on our current RFP, we will be evaluating whether another PBM might be able to have a greater effect than our current PBM, using the limited tools allowed them. Remember, we can't change members' benefit plans, but we are allowed to influence physician and pharmacy providers' behaviors and practices."*

Cost containment strategies

Increasingly, PBM clients are employing two strategies to contain costs: hiring of pharmacists to perform clinical management/oversight functions and use of health benefits consultants. Clients stated that their PMPM drug costs were increasing largely due to drug price inflation and inadequate monitoring of PBM activities. To deal with these problems, four clients hired full-time pharmacists and two clients were actively considering this course of action:

> *"PBMs have their own agenda, an agenda quite different from their health plan clients. So we wanted to keep actual management of the pharmacy benefit in-house."*

Some PBM clients stated that their in-house pharmacists perform two functions: oversight of PBM activities and development of cost-cutting initiatives based on analyses of PBM data. In-house pharmacists may work in collaboration with PBM staff to analyze the drug use and expenditure reports generated by the PBM to initiate activities designed to decrease expenditures. These activities include, but are not limited to, adding more drugs to prior authorization status, developing programs to educate physicians about the formulary, improving the formulary, tracking high-cost drugs, developing "patient-friendly" guidelines about the value of lower-cost prescription drugs, and developing

clinical drug-treatment guidelines for physicians. One client surveyed believed that hiring a pharmacist contributed to a slower rate of increase in PMPM costs:

> *"In my history with this health plan, we had increasing PMPM costs every year, until we hired our own pharmacist. Since hiring the pharmacist, the PMPM has been flat. Further, in specific targeted areas, we have documented decreases in overall medical care costs."*

Some clients are pursuing a general strategy of bringing management of the clinical and other PBM services back into the health plan. One PBM client described its approach: it establishes pharmacy pricing, designs and manages its own formulary, loads that information into the PBM's computer system, contracts with in-state pharmacies, and performs retrospective drug utilization review. Other clients are anticipating this transition:

> *"In the future, we'll shift some [PBM] functions back in-house and start renting [pharmacy] networks."*

> *"The PBM understands that we will explore the possibility of performing some or all PBM services 'in-house' in the future."*

Other clients did not foresee a future shift of the pharmacy benefit to an in-house function. The overwhelming majority of clients maintained that PBMs' claims processing capabilities and national network development could and should not be replicated internally. In a period of excess supply of claims processing companies, fueled by the growth of PBMs and "pure" claims processing companies, insurers reason that it is cheaper for them to "buy" than to "build" a claims processing infrastructure.

To control costs, clients also are making increasing use of health benefit consultants. Typically, consultant services are used when contracts are being negotiated, although some clients are engaging consultants to monitor whether the terms of the client's contract are being fulfilled by the PBM.

Consultants are described as "major drivers" in the PBM industry, guiding clients to create contracts with greater numbers and varieties of savings guarantees, to affix financial penalties for failure to attain performance standards, and to use aggressive pricing strategies to ensure discounts from pharmacy networks and high rebate return levels from pharmaceutical manufacturers.

Quality

As in other sectors of the health care arena, competition among PBMs for clients largely centers on price, not quality. Purchasers (i.e., plan sponsors) are not insisting on sophisticated quality measurements and reporting requirements from PBMs because their

attention is riveted on containing drug costs. Further, clients expressed the opinion that there is a lack of valid, useful, and standardized quality-of-care indicators in the pharmaceutical field. In the drug arena, few quality-of-care outcomes indicators exist. HEDIS measures are considered inadequate by purchasers and PBMs alike, typically because they are too process oriented or too general to have any predictive value.

In addition to competing for clients on price, PBMs also compete on several non-price aspects of care, including consumer choice of providers, access to medications, and satisfaction/customer service. Consumer choice focuses on network breadth, whereas access includes such factors as distance to the pharmacy. Customer service and satisfaction emphasizes large-scale satisfaction surveys, assessments of timeliness of pharmacists' services and patients' reporting of counseling from pharmacists. Some clients equate quality of care with members' satisfaction with customer services:

> *"We have dedicated customer service units at our PBM. Our quality requirements concern: 'x' percent calls are handled within 'x' time interval, or standards about telephone blockage, abandonment rate, prescription processing efficiency, accuracy of dispensed prescriptions. The PBMs could be penalized financially for failure to meet these standards, depending on the contract."*

Another managed care organization reported that the PBM's lack of timely reporting to the MCO's quality assurance committee resulted in financial penalties for the PBM. The health plan reasoned that failure to report systematically on physicians' prescribing errors, and/or failure to submit online reports that identify missed interventions by the pharmacist, compromised its ability to provide feedback to physicians and pharmacists about their prescribing and dispensing patterns and costs. These "quality" indicators are used by some plan sponsors to identify physician and pharmacist outliers who are then targeted for educational outreach efforts. In some instances, such reports can inform a health plan's decision to terminate physicians from its plan or a PBM's decision to terminate pharmacies from its network.

Exclusivity versus multiplicity

All but two of the plan sponsors had contracts with only one PBM. At the time of the interview, one of the two plan sponsors with multiple PBM contracts was in the RFP process and noted that efforts were being made to "consolidate our business with one vendor with whom we would be able to obtain lower prices." The other plan sponsor indicated a preference for maintaining more than one vendor:

> *"We like having two vendors [one for retail and one for mail] because they compete with each other within our contract. We can play one against the other. Moreover, if one is in trouble, the other can put its resources into operation to pick up the slack."*

This plan sponsor acknowledged, however, that there were disadvantages of two vendors: more administrative effort with two contracts and less leverage with pharmaceutical manufacturers. One further disadvantage might be problems in merging utilization data. However, the health plan stated that the two PBMs exchange utilization data for P-DUR and R-DUR on a daily basis and that this operation has been working efficiently.

Consolidation

Consolidation in the purchaser sector: employer coalitions. The PBM industry is witnessing increasing consolidation. This trend is evident in the purchaser sector. In an effort to achieve greater leverage with PBMs and try to cope with increasing drug costs, employer coalitions at the local, state, and national levels are offering pharmacy benefit management programs through PBMs. Most of these programs offer open formularies. Some offer differential co-payments and prior authorization functions, but these are employer-specific.

On the state level, some employer coalitions have banded together and established state-wide PBM initiatives. Finally, on the national level, a major employer coalition developed an RFP and disseminated it to PBMs with the capacity to respond to a national product. The RFP was released in response to newer coalitions being unable to respond as quickly as established coalitions in developing and offering a PBM product; further, it is anticipated that a national product would centralize the knowledge base and the work involved in negotiating PBM contracts, whereas currently, each coalition has had to negotiate its own state-wide contract.

Consolidation in the insurer sector. A recent trend is toward greater consolidation in the insurance sector. Several regional Blue Cross/Blue Shield plans formed a holding company covering a large number of lives. It is anticipated that this consolidation will allow the insurers to realize greater economies of scale and give them greater bargaining leverage with PBMs directly and pharmaceutical manufacturers indirectly.

Attitudes about vertically integrated PBMs

Although the FTC approved the mergers of drug companies and PBMs, and the agency has not reported any evidence that vertically integrated PBMs are acting improperly, some clients voiced concerns. Half of the surveyed clients used the services of vertically integrated PBMs, and several expressed skepticism regarding the possible conflicts of interest in some vertically integrated companies. The following quotation is illustrative of client sentiments:

"One issue of great importance is the ownership of PBMs by drug companies. We all need to monitor this vertical integration closely. [One vertically integrated PBM] has gotten into trouble by pushing its drugs on the doctors. I have been very impressed that [another PBM] has not acted improperly. In the future, due diligence will be an important role for government. It will be a challenge to keep parent companies from interfering with their PBMs; thus far, two PBMs' pharmacoeconomics studies conducted in partnership with PBMs, or with PBMs' data, have focused on their 'pet' drugs."

Other clients had no complaints about their vertically integrated PBM and expressed no concerns that the firm's parent company was acting improperly.

Increasing sophistication of PBM clients

Several PBM clients indicated that they were becoming more sophisticated purchasers of PBM services. There was growing recognition that rebate monies could be returned in their entirety to the plan; that per prescription claims processing fees could be significantly reduced; and that PBMs could be held accountable to savings guarantees, particularly if risk-sharing arrangements were established:

"The key is in the contract. You have to put the vendor at risk in order to make them stand behind their guarantees regarding rebate monies, moving market share, and holding down costs. "

Clients are also beginning to realize that they lack the human resources to monitor whether PBMs are living up to the terms of their contracts. To overcome this problem, some clients are beginning to ask health benefits consultants to monitor whether PBMs are performing at the level agreed upon in their contract.

Greater sophistication of PBM clients also was evidenced in the selective ways in which they contracted for PBM services. In one case, the health plan was satisfied with the PBM because it closely analyzed the PBM's capabilities at a sophisticated level and made judgments about which services the PBM could provide well. The health plan only contracted for those services and chose to conduct much of the pharmacy benefit management in-house, via pharmacists. The health plan felt that contracts with PBMs are only as good as a prospective client's negotiating team and plan administrators are savvy and experienced.

Better contract terms were attributed to several factors. Some clients noted greater competition within the PBM industry itself, resulting from consolidation among PBMs and growing competition between PBMs and claims processing firms. Others observed that larger clients were making increasing use of benefit consultants who had represented other PBMs and could bring this experience to bear as standards for

negotiations for clients of all sizes. Several PBMs noted that pharmacists employed by the company could help significantly in the negotiation processes with PBMs, given their clinical and business acumen. Finally, there was growing recognition that by writing more explicit and demanding RFPs and contracts, problems with PBMs could be remediated.

Policy issues for Medicaid as perceived by PBM clients

Two plan sponsors indicated that one component of Medicaid programs for which the PBM industry is not meeting their needs is the absence of electronic claims systems for long-term care pharmacy. These plans asserted that PBMs do not have the capability to process these claims electronically because many items lack NDC numbers,[26] or they have many components with different NDC numbers. One plan sponsor spokesperson expressed concerns in the following manner:

"The First Data Banks of the world and the PBMs need to get together and expand their capabilities in this area -- go beyond retail pharmacy. Controlling costs in these sectors under the current fee-for-service system is nearly impossible."
Given the growing focus away from acute, hospital-based care to chronic, community-based care, the need for these kinds of data--both in the public and private sectors--becomes more significant.

Several clients recommended that if Medicaid wants to achieve cost savings it should capitate physicians for drugs in managed care settings. One plan spokesperson asserted that PMPMs under capitation can easily be half of what they are in the fee-for-service system. PBMs observed that their interventions to change physician prescribing patterns would be more powerful if implemented under a capitated reimbursement system.

Similarly, plans suggests that HCFA should examine the option of capitating pharmacies and paying for cognitive services using "long-term care" facility techniques, that is, monthly consulting by pharmacists in long-term care facilities as required by regulation. The general sentiment was that retail pharmacy must be held accountable for the care it provides, through sharing savings, internal risk sharing, or salary incentives. However, other clients acknowledged that this would be a challenging undertaking, because in the retail pharmacy setting the population is very mobile and there is generally no access to medical record data.

One plan sponsor suggested there could definitely be a niche for mail order which has not been developed in the Medicaid population, namely, long-term care populations and the aged. The plan sponsor noted that cost savings could be realized and that as the nation's population ages there will be increased demand among geriatric patient

[26]The NDC (national drug code) is a product identifer placed on all prescription drugs by the FDA and issued to the drug company. The NDC is an 11-digit code that identifies the drug, manufacturer (first five digits), the drug product including its strength (next four digits), and the drug=s package size, e.g., 100, or 1000 tablets (final two digits).

populations, since mail order services appear to be a preferred delivery option for some elders.

VI. Potential Impact and Roles of PBMs: Medicaid and Other Government Programs

Many of the benefit structure components and drug use management techniques employed in drug programs administered by PBMs effectively are present in or adaptable to Medicaid programs. Medicaid programs typically have state-wide panels of pharmacies as providers, defined program coverage, cost sharing in the form of modest co-payments, formularies defining covered drugs, generic substitution incentives via MAC programs, prior authorization, rebates, and DUR programs. Since Medicare operates as an insurance program rather than an entitlement program, and most PBMs likely include at least some elders in their covered populations, PBMs could be a relevant option for a potential drug benefit under Medicare.

Although what PBMs are and do have some parallels in Medicaid programs, there are some important distinctions. For example, when co-payments are present in Medicaid fee for service programs, the co-payment amounts usually are nominal amounts, typically less than $1.00, much lower than those in most PBM plans. Also, Medicaid programs do not have differential co-payments to foster target drug use, such as for generic or formulary drugs. Requiring patients to cover the difference in cost between generic and brand name versions of drugs drives generic dispensing rates up in PBM plans, likely similar to mandatory generic provisions in State Medicaid programs (e.g., MAC provisions). Medicaid recipients may not be able or willing to pay the cost difference if such a requirement were present a State's drug program.

Medicaid Interest in and Experience with PBMs

Pharmacy consultants at six state Medicaid programs were interviewed to identify the extent to which their state had contracts with PBMs and their interest in doing so. Their opinions about potential advantages and disadvantages of using PBMs to run or manage the state's drug program were ascertained. The states were queried about both direct contracting with PBMs (to turn over the drug program to a PBM to manage) and "indirect" associations with PBMs where the contract with the PBM(s) was secondary, as a result of enrolling Medicaid recipients in MCOs and the MCOs having PBMs involved to manage the drug benefit. We selected states that we believed had interest or experience with direct contracting with a PBM, or that had a high number of Medicaid recipients enrolled in MCOs, hoping to get impressions about secondary relationships with PBMs through the MCOs.

1. Direct Contracting between State Medicaid Programs and PBMs

Of the six states contacted, none of the Medicaid programs have contracted directly with PBMs to manage their drug benefit. Most indicated there was a lack of data to support a net savings over existing Medicaid management. States who attempted to advance PBM management of the drug benefit were met with strong opposition from pharmacists and

pharmacy organizations. One state that proposed carving out the drug benefit and contracting with a PBM had the proposal rejected twice, once by the Governor and once by the legislature. In another state, a study was authorized by the legislature to evaluate potential savings from selectively contracting (carving out) several services (including prescription drugs, hearing aids, DME, home health services, etc.). The study was inconclusive. They estimated that implementing a contract with a PBM conservatively could yield a potential loss of $6 million to a gain to $2.7 million. They recommended the state proceed with a competitive bid to assess potential savings opportunities and proceed accordingly (Washington Department of Social and Health Services , 1994).

Advantages

States reported that PBMs potentially could reduce administrative costs (e.g. claims processing, formulary administration, network contracting) to the agency. States cited reduction in political pressure on formulary decisions and ability to restrict the pharmacy network as other potential advantages of using PBMs. Several pharmacy consultants thought that competition by PBMs for the state contract would give the states greater leverage in directing the terms and conditions of the contract (e.g., lowered capitation rate, lower administrative fee per claim for processing and adjudication). Also, if risk contracts with PBMs were arranged, it would permit the state to have a firm budget estimates.

Concerns

All pharmacy consultants expressed concern that PBMs could not provide drugs at a lower cost than Medicaid was able to secure under OBRA '90, particularly in regard to the rebate policy. Three states expected their net cost for drugs to be no more than their current cost under the rebates, regardless of what PBMs were able to do (e.g., extensive "switch" programs, formularies, or mail order).

Pharmacist consultants fear that rebates will be unavailable under PBMs. The Pharmaceutical Manufacturer and Research Association (PHRMA) lobbied to sunset the Medicaid rebate provisions without success. There is concern about potential additional rebates being implemented by states, such as California's use of supplemental rebates on top of statutory rebates for drugs in a limited number of classes. Approval must be obtained from Medi-Cal for covered drugs not included on the Medi-Cal List of Contract Drugs.

Most state consultants were not concerned about having an adequate pharmacy network either via restricted networks or a decreased willingness to participate in the program. However, one consultant thought lower rates offered by PBMs may require case by case pharmacy negotiations to maintain access in certain urban and rural areas.

Several potential barriers to contracting with a PBM for the drug program arose. They included: 1) existing contracts to process claims would have to be renegotiated (including claims for other services that would be at a much reduced scale level without

drug claims); 2) HCFA waivers would have to be sought; 3) PBM denial of claims because of failure to use a required generic or formulary drug, refill too soon, or claims not filed on a timely manner (caused by a Medicaid practice of providing retroactive eligibility) may result in many appeals to Medicaid; and 4) inability to use co-payments to reduce drug costs in the same way PBMs use them in the private sector (e.g. high and/or differential co-pays to direct usage toward preferred drugs).

2. Indirect Associations between State Medicaid Programs and PBMs (via MCOs)

All pharmacy consultants mentioned a primary interest in their state was expanding the use of MCOs for Medicaid recipients. The majority of Medicaid eligibles being enrolled in MCOs are AFDC recipients, although states are attempting to enroll aged, blind, and disabled recipients also. Florida offers eligibles the option of choosing a case manager or an MCO; the majority choose a case manager, 25 percent are in MCOs. Wisconsin has 25 percent of Medicaid eligibles in MCOs, nearly all of whom are AFDC. Overall in California, 20 percent of Medicaid recipients are in MCOs. California's latest Medi-Cal strategic plan calls for contracting with two MCOs in 12 of 58 counties, five counties have "county organized health systems" wherein a county-sponsored organization has taken over Medi-Cal administration; and in two other counties (Sacramento and San Diego), the state contracts directly with multiple managed care providers encouraging county agencies to form managed care networks (e.g., Healthy San Diego network, multiple MCOs in Sacramento).

Two states reported carving the drug benefit out of the MCO contract and continuing to manage it themselves. In other states, the drug benefit was managed by PBMs via subcontracting with some of the MCOs. Three states required contracts with managed care organizations pay no more for drugs than the net amount paid by Medicaid (paid amount less rebates).

Performance Evaluation

Although all the six states have required MCOs to provide encounter data to be used by Medicaid to evaluate care, few, if any, have received the information (none of our interview subjects reported receiving them). Most request HEDIS measures and none of the MCOs have developed special drug reports. Medical and financial audits are done by two of the states. The pharmacist consultants had little involvement in developing or monitoring drug therapy under managed care. Some thought it was the responsibility of the MCO or their PBM. Others indicated that the current priority was to get people enrolled in MCOs and that evaluating what occurred within the MCO was secondary (as long as PMPM costs were in control).

Pharmacy Benefit in MCOs vs. Medicaid

Some state consultants mentioned that MCOs use formularies to manage the drug benefit, an intervention not permitted by Medicaid regulation. In one state, the pharmacist consultant monitors the formularies of all 24 MCOs with Medicaid recipients enrolled to ensure necessary drugs were available. However, in most states, the pharmacist consultants are not aware of formularies being developed by MCOs.

It is interesting that in most states that have modest Medicaid co-payments (e.g., for prescriptions) they do not permit MCOs to implement co-payments, perhaps as a means of inducement for recipients to enroll in MCOs.

Potential Impact of PBMs on State Medicaid Programs

Areas of potential impact of PBMs on cost and quality in State Medicaid programs are outlined below.

1. Pharmacy Payment

Relative to current Medicaid payment levels, PBM reimbursements to pharmacies are lower, both in dispensing fees and EACs. Reduced pharmacy reimbursements for Medicaid programs may move payments closer to "market" rates, since third-parties and PBMs represent a large proportion of sales in pharmacies.

Cost Impact

The cost impact for Medicaid can be estimated roughly as follows:

Dispensing fee

PBMs typical fees were in the $2.50 - $3.00 range ($2.50 was the norm)
Medicaid Average = $4.12 (Range = $2.50 - $5.77)
Difference = $1.62

Discounts from AWP (EACs)

PBMs typical discounts were AWP - 12% or 13% (depending on Panel)
Medicaid typical = AWP - 10%
Difference ~ 3% of AWP

Quantification:

Avg RX payment:	$25.00 (assumed total pay, with co-pay)	
less Avg Fee	$4.12	
EAC (AWP - 10%)	$20.88	AWP = $20.88/.90 = $23.20
AWP - 13%	$20.18	
Difference	$0.70	

Total payment difference per RX ~ $2.32 (9.3%)

Note: this estimation does not consider differential fees for generic prescriptions or fee adjustments that may be necessary to ensure sufficient providers in geographic areas.

Quality Impact

The quality impact of reduced pharmacy payments will be related to the sequelea of the change. Pharmacies that cannot continue to be financially viable may exit the market leading to access problems for beneficiaries. Quality of care may decrease as pharmacies try to reduce costs by increasing efficiency in prescription processing, decreasing patient contact time with pharmacists and reducing professional time evaluating therapies and drug use.

2. Maximum Allowable Cost (MAC) Programs

Cost and quality issues relevant to MAC programs revolve around the number of MAC drugs, the level of MAC amounts, and the speed of setting or adjusting MACs in PBMs relative to Medicaid programs. Are the numbers of drugs more or less, the levels higher or lower, and the speed quicker or slower?

Cost Impact

The PBMs reported using HCFA MACs as a baseline or starting point and adding or removing products. Since generic dispensing is a major factor in generating program savings for PBMs, one would surmise they are prompt to add new products to their MAC lists when patents expire. Also, the price differentials between brand and generic versions of drugs suggest they would pay close attention to price changes and reflect such in their policies promptly. The impact of PBMs on generic dispensing likely would be marginal compared to Medicaid programs, only due to more rapid additions to MAC lists (if such occurs); current state MAC programs provide high levels of generic dispensing for multi-source drugs. Also, Medicaid obtains rebates of 11 percent on generic drugs.

Quality Impact

If MACs are established for drugs with equivalency problems (e.g. not A/B rated), therapeutic failures are possible. Other quality aspects may occur (e.g. attitudinal preference for brand products and resulting psychological distress in a mandated generic (MAC) program), but likely will be less prominent, since generic substitutes are accepted relatively widely by prescribers and patients.

3. Rebates

The level and number of products covered by rebates may be reduced if PBMs are chosen to manage State Medicaid programs.

Cost Impact

Based on HCFA rebate data (3rd quarter FY 1994-95 data), Medicaid experience is approximately 18 to 21 percent of drug spending is rebated.

This percent of rebate is higher than that reported by PBM respondents ("10 percent good, 17 percent on some;" "9 percent to 10 percent on brand;" "about 90 percent of what Medicaid gets;" "much lower than Medicaid"). Such figures are difficult to quantify. Although the number of PBMs interviewed was small, they represented a large proportion of PBM covered lives. The PBM responses suggest that Medicaid rebates would be at least a few percent lower with PBMs.

Also, the proportion of product rebated would be less. In Medicaid, essentially all products are rebated. In PBMs, rebates are not necessarily universal. Plus, the proportion of the rebates achieved would be different than at present. Since Medicaid programs (and HCFA) provide the administrative functions associated with the rebates, they now receive all the rebate, states via proportional share with HCFA. If PBMs administer the rebates, they likely will withhold a portion as "administrative fees" (they reported "20 to 30 percent administrative fee"; "90 percent back to the client").

The connection between rebate level and moving market share is noteworthy. Can the same success in moving market share be accomplished within a public program with low potential cost sharing provisions?

Also, a concern about "rebate myopia" is worth mentioning. States that focus attention on rebates might overlook the importance of overall net drug cost. Do rebates drive use of more expensive agents? The real issue is average cost, or even overall medical costs that may or may not be connected to rebates and use of rebated products. Interestingly, average prescription costs tend to be lower for Medicaid than other third-party prescriptions, suggesting a different mix of products used in Medicaid programs. Would this pattern continue with PBM administered State programs?

One PBM was particularly vocal on the importance of looking beyond rebates.

"Rebates are only one dimension of cost savings. Utilization is another. One of the basic laws of health care is that if you really want to control costs, you have to control both costs and utilization. The states have the rebates on all drugs and that certainly reduces their drugs costs. But they really don't have a handle on utilization. States cannot always buy the cheapest drug (presumably referring to rebates associated with market share movement) and they cannot control utilization as we do." (referring to their ability to influence patient behaviors through differential co-pays, formularies, pharmacist interventions, etc.).

Quality Impact

The association between rebates and efforts to move use to those products raises potential quality of care issues. Are the drugs targeted for use because of rebate parameters the best drugs clinically? Do interventions to direct market share to preferred products interfere in patient provider relations detrimentally? These questions may not be answerable, but reflect the thorny issues potentially associated with rebates and associated drug use movement programs and initiatives.

4. Restricting the Panel of Pharmacies

To obtain price concessions from pharmacies, or to achieve a performance based panel of pharmacies, PBMs may restrict the numbers of pharmacies participating as providers.

Cost Impact

This could yield additional savings over and above those achieved from changing Medicaid pharmacy payment rates to "market" levels. The restrictive panels in PBMs often have a $0.50 or more dispensing fee concession, plus one or a few additional percent discount off of AWP for ingredient cost payment.

Quality Impact

Such changes could reduce access to pharmacy services for some recipients. If the restricted panels are predominantly chain pharmacies, access problems may be exaggerated. Independent pharmacies provide proportionately more Medicaid prescriptions and tend to be more represented in urban or rural areas where recipients reside. However, one might argue there are too many pharmacies, with some city blocks having two or three pharmacies.

If the panel is restricted to achieve enhanced performance, this could be a quality enhancing measure. However, few, if any, situations are present now where the pharmacy network is restricted to pharmacies meeting performance criteria. There might be promise long term for such restrictions to yield enhanced qualitative performance via the PBM, but there is a conflict between price and quality at present that might preclude qualitative performers to develop.

5. Mail Service Prescriptions

PBMs varied in the extent to which they promoted mail service pharmacies for dispensing prescriptions to covered beneficiaries. Consequently, the impact may depend on the degree that mail service is emphasized.

Can it be *inferred* that mail order is reducing cost and maintaining quality by the following findings?

A. purchasers are demanding mail order services and in some cases modifying incentives in drug benefit packages to encourage use of such services

B. consumer demand for mail order services is growing stronger in certain high-use sectors (particularly the elderly)

C. some PBMs recently acquired firms to incorporate mail order services into their "in-house" capabilities

D. one PBM reported twice the success rate for "switches" initiated by mail service than for those initiated in the retail network

E. mail order pharmacies obtain more rebate dollars and offer greater discounts to their customers than does retail pharmacy.

Cost Impact

Savings resulting from mail service pharmacies can be debated, as it has in the trade press and literature. Special Medicaid concerns include frequent eligibility changes, recipients with poor or no address to send drugs, more potential for waste or fraud among Medicaid recipients, lack of incentives to direct patients to use mail service, and inappropriateness of Medicaid populations for this distribution channel (AFDC having more acute needs, LTC using unit dose distribution, and chronically mentally ill needing more provider interaction). Mail service may provide enhanced switch rates to preferred drugs and yield savings that may accrue from directing use to those products.

Quality Impact

There are some potentially positive and negative effects of having Medicaid recipients receive their prescriptions by mail.

Positive Impacts:

There is potential in mail service to change physician prescribing behavior. The quality and accountability of pharmacists for communications and clinical interventions (with both patients and prescribers) could be enhanced and consistent through standardized pharmacist training. Patients may be more receptive to pharmacist messages if received in their home environment. There also could be greater efficiencies and reduced intrusion when contacting prescribing physicians.

Negative Impacts:

Mail service may result in recipients having less frequent contact with providers, since larger dispensing quantities are emphasized. More elapsed days between dispensing encounters could reduce the ability to monitor compliance and therapeutic effects in a timely fashion. Coordinating and providing consistent patient care can be more difficult when mail service pharmacies provide maintenance medications and retail pharmacies provide acute medications. The long distance nature of mail service pharmacist-patient encounters can yield more impersonal interactions that some patients might not prefer. Also, if disease parameters are manifested in physical signs and symptoms, it is more difficult to assess them in telephone interactions. These concerns are mitigated by studies showing that drug therapy counseling and monitoring activities do not necessarily take place in retail settings to the extent desirable.

6. Formularies (and Formulary-Related Activities)

Formularies and formulary related activities, such as prior authorization and therapeutic interchange can help direct product use to "desirable" (based on cost or quality aspects) agents.

Cost Impact

Product steerage to agents with better cost-effectiveness profiles, in terms of drug costs or overall medical costs and outcomes has potential for drug program or overall (long term) program savings. If the cost effectiveness advantages are bona fide and not merely rebate derived, the potential for savings may be strengthened. Unfortunately, objective evaluative data to base cost-effectiveness decisions are scarce.

If drug use control require pharmacist effort, while at the same time there is price compression for pharmacy payments, it may prove difficult to get pharmacists to comply with suggested efforts. Medicaid recipients cannot be incentivized to the same extent as in private markets, e.g. via differential co-payments. Medicaid co-payments are much small than the private market and are prohibited or severely restricted in Medicaid managed care contracts.

Quality Impact

In the PBM environment, and elsewhere, the implications of restricted formularies on quality of care and clinical outcomes are unknown. There is potential for positive and negative impacts on quality of care. It is especially important to integrate patient-specific data to inform prescribing and dispensing decisions.

PBMs are more insulated from political pressures than are Medicaid programs when developing formularies. This may allow them to consider quality aspects predominantly, however, the strong economic imperative of PBMs may compromise clinical issues, particularly if they are at the cost margin. PBMs and Medicaid plans that have assumed risks have implemented restricted formularies.

7. DUR (Prospective and Retrospective)

Cost Impact

Retrospective DUR can identify and intervene to change patterns of high cost or inappropriate use and patterns of fraud and abuse. There are many questions relative to PBMs versus Medicaid capabilities and success in this area, such as: are savings more/less than current Medicaid, are PBMs ahead or behind Medicaid in their capabilities, what are the costs to run programs vs. savings generated, and are there differential drug vs. total program cost effects?? In many cases, the PBM provides R-DUR information to clients who then analyze and implement their own interventions based on the data. The effort to conduct the DUR interventions would remain with the state, as is the case now. Also, some PBMs consider R-DUR as part of the basic set of services, but others consider it an "add on" at additional cost.

Some of the same questions are relevant for prospective DUR. Prospective DUR can intercept early refills, inappropriate use, fraud, etc., and it can be a tool for drug use to preferred products (& subsequent savings). Unlike PBMs, not all state Medicaid programs have POS systems (larger states do). Those states that implemented POS systems will have already incurred the development investment.

Quality Impact

DUR programs (both prospective and retrospective) have potential for enhancing quality of care by improving patterns of drug use. Prospective DUR can provide real-time adjustments to avoid drug problems and inappropriate or less effective therapies. Retrospective DUR and associated interventions can serve as an educational tool for avoiding future problems (if prescribers and/or patients are able to learn from mistakes once advised of them and suggested differently). Whether PBMs have better or worse DUR programs than state Medicaid agencies is unclear. Some state Medicaid programs have contracts for DUR programs with PBMs or firms supplying PBMs with criteria and services, thus the programs may be similar.

PBMs noted some pharmacists stated that they have very little time to respond to P-DUR messages (consequently the pharmacists often disregard due to the number of false positive alerts). Currently, PBMs have little recourse when pharmacists and physicians fail to respond to DUR interventions. PBMs provided very little information on "hit rates" -- the number of DUR alerts triggered by prescription claims. Some are not monitoring hit rates. They report basic data to clients, such as percent generics dispensed and average cost per prescription, but these data do not allow clients to assess quality-of-care.

8. Disease management

Disease management is in preliminary phases only. It is hard to estimate the impact on cost or quality. Disease management programs may increase drug budgets, but have a favorable impact on total costs. Data and experience are lacking for evaluation in the PBM industry, although there seems more movement in the private side than the public side. Problems integrating drug and medical data sets are present in both environments, although there may be more history and experience in Medicaid programs. Given differences in patient populations between PBM clients and Medicaid recipients, it is likely that patient centered initiatives will be less successful in Medicaid programs. A concern is whether disease management programs merely are veiled efforts to enhance the market share of PBM-owning drug firms.

9. Administrative Cost of Claims Processing

PBMs may be better equipped to achieve efficiencies and lower claims processing costs (charges). Current amounts paid by state Medicaid programs may be considerably above those engaged on the PBM side. Several respondents noted per claim charges less than Medicaid programs' experiences.

If prescription claims processing is shifted to PBMs, economies of scale may be reduced for other claims (e.g. medical) and the costs for these claims might increase (i.e. contractors would, in all likelihood, increase charges for processing these other claims).

Issues Raised by PBMs for Medicaid Programs to Consider

Medicaid could be characterized as the oldest pharmacy benefit manager in existence. A literature review of methods used to manage drug benefits in the ambulatory setting finds a major portion of the research is done with Medicaid populations. This likely is due to several reasons: 1) the non-proprietary nature of Medicaid programs, makes it easier for researchers to get access to the data; 2) the longer history of Medicaid as drug benefit manager compared to PBMs; 3) the availability of a Medicaid database of cost, diagnosis and procedure information for not only drug, but other medical claims; 4) State and Federal budget forces that long have driven Medicaid programs to seek new ways to reduce costs while maintaining access and quality; and 5) State and Federal interest in evaluating these efforts.

As the largest publicly financed drug benefit, Medicaid provides PBMs with an untapped market to sustain their growth. But, unlike some of the current clients of PBMs, some Medicaid programs are a sophisticated managers of drug benefits with diverse populations not traditionally managed by PBMs.

The following are issues that should be considered by States when considering contracting with PBMs for managing drug benefits.

Medicaid beneficiaries

Medicaid populations have different medical needs than traditional PBM populations and contain large proportions of high cost patients. Relative to the general population and PBM population in particular, Medicaid has a disproportionate share of chronically mentally ill, disabled, AIDS, and frail elderly patients and long-term care (LTC) residents. These populations more likely need services of specialists and may receive care from providers not commonly found in managed care networks (e.g., Community Care Organizations). These populations could benefit from guaranteed access to primary care providers in managed care, but may find access to specialty care limited by managed care programs' needs to control costs.

The disabled and elderly have other insurance (Medicare) which pays for most medical services but a limited scope and number of drugs (those subsequent to a physician office visit and administered or dispensed during that visit.). Children with special needs often have care paid by other agencies through Title V programs. Including these populations in managed care drug programs requires greater coordination.

LTC residents present a different challenge to PBMs not accustomed to managing institutional drug use. PBM provider network pharmacists may not have experience in unit dose dispensing commonly used in LTC facilities. Network pharmacists also may not be familiar with special consulting and drug regimen review requirements for LTC.

Many of the cost containment methods used by PBMs may not work with Medicaid populations. Mail order, which relies on larger supplies of medication to reduce pharmacist fees and administrative costs, may not save money if there are frequent changes in eligibility. Eligibility status tends to change frequently in the Medicaid AFDC population. With welfare reform, eligibility changes may be even more frequent and problematic.

PBM patient cost sharing incentives for formulary or preferred drugs are not transferable. Medicaid recipients have little discretionary income to spend on co-payments and non-formulary (i.e. non-covered) drugs. Also, Medicaid eligibles are accustomed to freedom of choice of providers, virtually unlimited access to prescription drugs (i.e., no formulary), and some are covered for OTCs. (Nine states cover "most" OTCs and 37 states cover "some" OTCs.)

Using restrictive panels of pharmacies to achieve lower program costs may not be feasible. Medicaid recipients are often dependent on public transportation to visit pharmacy and other medical providers, making network access important.

Medicaid programs

Unlike most PBM clients, Medicaid has years of experience in implementing and managing cost containment programs such as MAC, DUR, prior authorization, provider audit/utilization review. State Medicaid programs have internal pharmacist consultants with experience in claims processing and utilization review. Is a PBM a relatively unnecessary middleman for functions best performed by the State?

Medicaid, as a public program, is subject to greater political pressures, greater public access to policies and information than typical PBM clients. Are PBMs equipped to handle the challenges of advocacy groups that scrutinize policy and program impacts? Will PBMs be willing and able to respond to public access desires? Is it in the PBM's best interest to serve Medicaid populations if it must risk disclosure of proprietary DUR systems information (criteria) and concomitant loss of market advantage?

Some state Medicaid programs have a long history of linking drug and other medical data through their management information system and of generating management and utilization review reports from that database. PBMs make greater use of data in provider reporting, but rarely have comprehensive databases linking drug and medical claims data.

Medicaid has a Congressional-mandated rebate system backed by purchasing power of 13 percent of the total drug sales in the U.S. Can Medicaid maintain the rebate when PBMs administer the drug program?

PBMs

PBMs use restricted networks to secure reduced fees, while Medicaid provides access to all pharmacies agreeing to participate. Beneficiaries are guaranteed freedom of choice under Medicaid (except in the LTC setting, where the recipient's pharmacy access frequently is restricted by the nursing home). As a result, Medicaid has less leverage in establishing pharmacy reimbursement.

PBMs may offer some advantages to Medicaid programs. PBMs are not subject to formulary limitations imposed on Medicaid by OBRA '90. OBRA '90 requires each state to reimburse for all drugs for which HCFA has negotiated rebate contracts with the manufacturer. PBMs use formularies to direct product use towards less expensive therapies and to enhance rebate negotiations.

Some PBM clients noted that contracting with two PBM vendors can reduce short-term drug costs by fostering competition between the vendors. If Medicaid managed care plans are to consider this approach, they should consider that the presence of two vendors may compromise quality and continuity of care (e.g., different preferred drugs; different and often conflicting DUR criteria).

Private systems are more responsive than government bureaucracy to adopting new programs or technology. Despite 90 percent Federal funding for point-of-sale (on-line, real-time) claims processing and DUR, States have been slow to adopt this technology, whereas POS systems are the standard in PBMs. Those states that have adopted POS DUR generate large numbers of false positives (GAO/AIMD-96-72, 1996). Some PBMs have developed innovative and rigorous approaches designed to eliminate faulty DUR criteria (see DUR section). Disease management and academic detailing programs are being developed and implemented by PBMs, whereas Medicaid DUR programs have reported few activities in these areas despite OBRA '90 encouragement. PBMs use prescriber profiling to analyze drug use patterns, using them to target prescribers for intervention. The majority of Medicaid DUR programs continue to review individual patients rather than patterns of care, potentially redundant under a POS DUR system. Medicaid has been slow to adopt advanced data management systems.

Current and Potential Role in Medicaid

PBMs provide services to Medicaid recipients to a very limited extent. No states have contracted directly with PBMs to manage the Medicaid prescription drug program. Several states have indirect contracts with PBMs through MCOs that have enrolled Medicaid recipients as part of states' managed care initiatives, but not all MCOs use a PBM to manage the drug benefit. Medicaid recipients enrolled in MCOs tend to have fewer prescription drug needs compared to other Medicaid populations. In sum, a relatively small number of Medicaid recipients use PBM services, except in Tennessee, where PBM RxCare is the primary drug program manager for Medicaid recipients enrolled in MCOs as a part of TennCare.

Potential Role

Some PBM services are potentially relevant for Medicaid programs. PBMs have sophisticated claims processing and data systems for handling administrative aspects of Medicaid drug programs. Their prospective and retrospective DUR and prior authorization programs parallel current state programs and possibly are based on the same criteria and algorithms. Formulary development and management programs also might be transferable to Medicaid programs.

State Medicaid programs may wish to consider individually the component parts of a PBM service package, rather than approaching a PBM contract as "all or nothing." Mail order dispensing could have shortcomings for Medicaid populations, as may drug use management techniques involving financial incentives for patients. There also may be difficulties in managing the drug benefit for long term care residents, since PBMs historically have not had experience with these populations nor the drug distribution systems used for these groups. States would be advised to maintain or possibly strengthen their oversight capabilities, as several PBM clients noted that proper oversight maximizes the utility of drug programs.

Current and Potential Role of PBMs for Medicare and Other Government Agencies

MEDICARE

Current Role

At present, there is no "current role" of PBMs in the Medicare program, since outpatient drug coverage is excluded in Medicare benefits. There likely are a number of Medicare beneficiaries receiving drug coverage that is managed by a PBM, but only

through supplemental Medicare insurance policies that include a drug coverage rider, or Medicare managed care plans.

Potential Role

If a drug benefit is added to Medicare coverage, there could be a role for PBMs in filling the void at the federal level to provide and manage the drug benefit. The Medicare program could benefit from efficient and flexible drug program design offered by PBMs. PBMs have gained experience with Medicare populations through administering managed care, indemnity insurance or employer benefit programs that include Medicare-eligible persons among their covered populations.

PBMs possess the infrastructure to manage a Medicare drug benefit such as prior authorization, formularies, and differential co-payment to encourage generic use or formulary compliance. Both beneficiaries and the Medicare program could benefit from on-line PDUR alerts to pharmacists for drug interactions and other problems. Drug-drug interactions, duplicate therapy, drug abuse, drug overdose, patient compliance and other problems may be averted, thereby improving patient health outcomes and reducing the use of hospital, physician, and other services. These capabilities have the potential to improve quality of care for Medicare beneficiaries.

Cost containment efforts used by PBMs also may be applicable for a Medicare drug benefit. Patient financial incentives can be used to foster use of cost effective therapies, since Medicare is an insurance-structured program and beneficiaries are not indigent, although some have limited financial resources. The cost effects of drug use management techniques would be desirable, particularly if they simultaneously maintain or improve quality of care. Pharmacy reimbursements could be established at market rates reflecting costs of providing care among efficient providers. Mail service prescriptions may be practical and even accepted by Medicare beneficiaries for greater convenience. Rebates would help assure the Medicare program achieves purchasing efficiencies for dispensed drugs. Much would depend on the content of the new legislation, i.e., the inclusion of a rebate program similar to Medicaid's rebate program.

Although there are some potential prospects for PBMs to manage a drug benefit under Medicare, there are some caveats. HCFA has limited internal pharmacy expertise for monitoring the management of a drug benefit. Medicare would be far larger than any other PBM client and likely would have different demands than traditional contracts. Without risk sharing or capitation, PBMs have reduced incentives to manage costs and utilization. Contract oversight would be critical responsibility for HCFA.

Competitive bidding by PBMs for management of such a large population likely would ensure a low cost contract. It also may result in greater consolidation in the PBM industry with potential for a reduction in future competition.

The impact of a PBM-managed Medicare drug benefit on pharmacists, pharmacies and the rest of the pharmaceutical industry would be much greater than the impact of a PBM-managed Medicaid drug benefit. Unlike Medicaid populations, which could be characterized as a marginal source of business, Medicare beneficiaries represent a major market for pharmacies, PBMs, drug manufacturers and other drug industry constituents.

If pharmacies extend network discounts to PBMs for the Medicare population, there will be lower margins, more emphasis on reducing operating costs (and, probably as a result, reduced quality of service), and continued consolidation or compression in the retail pharmacy market. Expanded use of mail service pharmacies also will cause consolidation. Beneficiaries will have reduced access as the industry consolidates. Ultimately, consolidation could result in decreased competition, with resistance to price discount pressure.

If manufacturers are required to extend the HCFA contracted rebates and provisions to covered Medicare prescriptions, their margins also will be eroded, without necessarily any corresponding increase in market share, as per many current PBM rebates, unless some manufacturers do not participate in the Medicare drug program. Eroded margins may lead to lower profits in the drug industry, reduced expenditures for research and development (and/or marketing), and continued industry consolidation. Consolidation in the pharmaceutical industry also can result in decreased competition and potentially decreased access to a variety of pharmaceuticals.

Structuring the rebates according to the HCFA contracted rebates also may have a chilling effect on PBM interest in the Medicare benefit, since rebates often are a part of PBM revenue streams. Without the ability to "share" in the rebates with clients, PBM charges will reflect their full costs of operations.

VETERAN'S ADMINISTRATION

The Veteran's Administration (VA) ambulatory pharmacy service has applied many of the drug management strategies used by PBMs and consequently has captured many of the economies. The VA has a centralized, efficient mail order operation; a restricted network of VA pharmacies; and a formulary with contracted drug prices and depot purchasing. A recent GAO study, *VA Health Care: Opportunities for Service Delivery Efficiencies Within Existing Resources* outlines its plans for establishing a PBM function as part of the VA (GAO 1996). By contracting with a PBM, the VA may obtain some incremental benefit from qualitative aspects of PBM activities, such as enhanced DUR, formulary development and management, and disease management.

FEDERAL EMPLOYEES

The drug benefit for Federal employees already is managed by PBMs. Conceivably, this PBM-managed population could be a valuable resource for evaluating the impact of PBMs on cost and quality.

VII. Impact of PBMs on the Larger Pharmaceutical Market

PBMs may have significant effects on several participants in the drug-use process. In the following section, we hypothesize about the impacts of PBMs on pharmacies, drug manufacturers, wholesalers, pharmacy benefit consultants, physicians, and patients. Given their central roles in the drug-use process, we hypothesize that the greatest effects of PBMs will be on pharmacies and manufacturers.

The potential impact of PBMs cannot be predicted with certainty. In part, this uncertainty stems from probable flux in the nature and role of PBMs. The impacts described below are relevant assuming that PBMs serve in their current capacity as vendors for a carved-out pharmacy benefit. However, some industry insiders have predicted that successful PBMs will more fully integrate themselves into the medical benefit, to work in close collaboration with health plans and providers -- ultimately becoming a "carved in" benefit controlled by insurers or managed care organizations. Other analysts predict that PBMs have the expertise, capital, and infrastructure to become leaders in the field of disease management, outcomes reporting, and cost-effectiveness analysis. This scenario assumes that PBMs are fully integrated into medical organizations.

Under the current scenario, pharmacies and pharmacists working in them may be one of the groups most affected by PBMs, since they provide the care that PBMs attempt to manage. The impacts of PBMs on pharmacies and pharmacists occur in financial, market, and care aspects of pharmacy operations and service provision. Individual potential impact areas and effects are described below.

Pharmacies

Reduced reimbursement

Reimbursement levels offered by PBMs reflecting volume-discounted pricing have an immediate effect on revenues and profits in pharmacies. PBMs represent a substantial proportion of a pharmacy's business; currently, 56 percent of pharmacy sales are paid by a third-party and 24 percent of sales are managed by a PBM. PBMs have been aggressive price makers in prescription drug markets. Pharmacy margins and profits reportedly have declined, threatening the viability of some providers. This could lead to concentration in the number of pharmacy outlets and ownership consolidation as marginal firms exit the market or are absorbed by other firms. Consolidation, largely through horizontal organization, is likely to continue as a trend in the chain pharmacy sector, whereas independent pharmacies are more likely to exit the market.

Restricted pharmacy panels

Pharmacies excluded from restricted panels have reduced revenue streams from dispensing fewer prescriptions, and reduced scale of operations. As PBMs grow more sophisticated regarding the measurement of pharmacist performance on quality and cost domains, there will be a growing trend toward more "performance-based" pharmacy networks, particularly in the managed care sector. However, this trend may be mitigated in those 31 states with any willing provider laws, as well as by employers' preferences not to limit pharmacy access for their employees.

Mail service prescriptions

As the population ages, there will be an increasing demand for mail order services from the elderly population, as well as from purchasers of health care (i.e., Medicare, employers). Mail service dispensing removes prescription volume from community pharmacies, having the same impact on revenues and scale economies as do restricted panels. Mail service pharmacies gain from market share diverted to them, but as PBMs incorporate mail service prescription operations in-house, independent mail service firms will lose business.

Drug use management interventions

Drug-use management interventions include formulary interventions, P-DUR, prior authorization, generic substitution, and therapeutic interchanges. These activities require extra effort by pharmacists, interrupting the dispensing process work flow. The resultant effort and cost are absorbed by the pharmacy, having a secondary financial impact on profitability. There can also be negative consequences for the prescriber and the pharmacist relationship if the pharmacist continually calls the prescriber with changes based on PBM requirements (especially when there are conflicting requirements among PBMs).

If rebates continue to drive the PBM market, and if they play a significant role in formulary decisions, then there will be continued emphasis on the pharmacist as 'formulary implementer.' Such a role precludes the pharmacist from performing a clinical function where his or her own judgment and experience operate in the patient's best interest. However, some analysts predict that rebates will become less prevalent, and that pharmacists and physicians will be capitated for drugs. Under these conditions, pharmacists may have professional and financial incentives to perform clinically-oriented drug management interventions.

On-line claims adjudication

This can increase efficiency in the claims/payment cycle, providing assured revenues and potentially enhancing cash flow. It also increases communications between pharmacies and claims processing entities.

Payment for cognitive services

Such payments reflect an alternate revenue stream for pharmacies and professional opportunities for pharmacists. If cognitive services continue to be defined as switching to the formulary product, pharmacy revenues may increase but professional opportunities will decrease. However, if cognitive services are more broadly and clinically defined, the provision of such services can result in greater revenues and professional opportunities for pharmacists.

Disease management programs

Similar to cognitive services, disease management programs can provide an opportunity for revenue and professional development. However, they may introduce additional competitors, since physicians and nurses also deliver disease management services.

Pharmacists in managed care settings can play a leading role in the provision of disease management services, particularly for those conditions in which chronic drug therapy is the treatment of choice. However, under conditions in which pharmacists are marginalized and not integral to managed care organizations, community pharmacists (in both chain and independent pharmacies) will not be able to play a leadership role because of the absence of diagnostic and other clinical information, as well as the "disconnect" between the pharmacists and the other members of the health care team.

Performance evaluations, criteria, and qualifications

Assessments of performance and/or specifications for participation may reward qualifying firms with business and remove others from the market.

Pharmacists

The impact of PBMs on pharmacists will differ depending on demand for their services. Decreased demand for pharmacists and pharmacist services will result from increased use of pharmacy technicians; "automation" of clinical processes into computerized systems; aggregation of dispensing functions to outlets with production scale efficiencies (e.g., mail order services, consolidated chains); and growth of 'physician connectivity' programs in which physicians receive electronic feedback regarding the appropriateness of their drug-therapy decisions prior to prescribing.

In contrast, there may be increased demand for pharmacists resulting from enhanced patient education efforts as part of disease management services and other disease management interventions. Further, there potentially can be demands for

increased clinical and professional skills by pharmacists, along with enhanced computer skills and systems capabilities. Finally, performance evaluations for quality of care will put pharmacists in the spotlight to perform at high levels of care.

Manufacturers

For manufacturers, the potential impacts primarily will revolve around one area: rebates (and market share changes associated with them). Rebates yield reduced prices and potential profits for manufacturers, since they are price concessions, but increased volume may result in enhanced revenue streams. The market share shifts and product movement changes associated with rebate arrangements may result in impacts described below.

Throughout the study period we witnessed greater horizontal integration within the pharmaceutical industry, and several analysts predicted that this trend will continue. Such integration is designed to achieve production and marketing efficiencies; to ensure broad product lines and drug coverage; to maintain market power; and to serve as a countervailing force against the growth of PBMs.

Integration is also occurring vertically. While further mergers between pharmaceutical manufacturers and PBMs do not appear likely, other kinds of alliances between industry and PBMs are emerging. One example is partnership between PBMs and manufacturers for the joint development and implementation of disease management programs. (PBMs are developing alliances not only with manufacturers, but also with medical groups and pharmacies.) These varying contractual and ownership relationships enable manufacturers to maintain some control of drug distribution channels; direct drug product use; achieve production/marketing efficiencies, and change marketing emphasis (from prescriber to PBM/formulary decision maker).

Research and Development

PBMs' aggressive pricing and rebate strategies can result in reduced profits margins and create market shifts that can put pressure on manufacturers' research and development budgets. Further, interviewees noted that PBMs have resulted in less development of "me too" products and a concomitant emphasis on "blockbuster" drugs (i.e., new therapies).

Other potential impact areas are present, but they are less substantial than those that will be rebate/market share driven. PBMs have an increased emphasis on generic drug dispensing as a cost-savings strategy. This may strengthen firms within the generic industry and divert the market toward generic drugs. For major manufacturers that own generic drug firms (as many do), this can be a mixed blessing; increased generic use detracts from their newer, research-based products but increases revenues in another department or subsidiary. For PBMs owned by drug manufacturers, this phenomenon

creates an internal conflict; new products and advanced technology may be in conflict with goals of reduced drug costs through generic use and slowing the adoption of new agents (especially when objective cost-effectiveness evaluations of new, incremental therapies are absent). This last phenomenon also fuels the emphasis on outcomes research and cost effectiveness evaluations of therapies on clinical outcomes and quality of life. "Proving" drug agents in a carve-out, drug cost only approach or in an integrated, total medical cost approach will become a prerequisite to market success.

There also is a potential conflict within the drug industry itself, namely, the PBM "haves" versus the PBM "have nots." The potential for vertically integrated firms to give competitive advantage to their own products on PBM formularies is a concern expressed by many respondents in the study. The FTC "firewall" provisions are intended to mitigate such advantages, but the long-term success of these sanctions are unknown.

Drug firms may have more incentive to move products from prescription to non-prescription status, to allow expanding markets, especially markets not governed by PBM drug use policies (such as non-prescription drugs that typically are not covered in PBM plans). More direct-to-consumer advertising might occur to create patient demand for prescription drugs.

Limited distribution of drugs also may occur, if pharmacy panels are restricted. This would reduce the distribution channel and number of outlets for manufacturers' products.

Wholesalers

Wholesalers are indirectly affected by factors influencing their customers (independent and chain pharmacies) and their suppliers (pharmaceutical manufacturers). Implications for these two groups will spill over into the wholesaler market. For example, pharmacies (both independent and chain) comprise a majority of wholesalers' businesses. Changes affecting the prescription market share and/or profitability and viability of community retail pharmacies and the number and mix of such firms in the market will be felt by wholesalers. Mail service pharmacies are not drug wholesalers' primary customers, thus prescriptions diverted to PBM in-house or contracted mail service pharmacies will result in reduced sales volumes for wholesalers.

Wholesalers also may see changes in purchasing arrangements with their manufacturer suppliers. Discounted sales prices to PBMs (via rebates) may result in reduced advertising allowances, fewer deals, and promotional program dollars for wholesalers.

Conceivably, wholesalers may become a acquisition target for PBMs seeking vertical integration, especially if merging with a manufacturer is disallowed.

Benefits consultants

Benefit consultants play an intriguing intermediary role in the PBM industry. They can be very influential, serving as advisors to PBM clients (employers, MCOs, etc.) soliciting contracts with PBMs, and as evaluators of PBM performance. They have played a role in enhancing competitiveness of PBMs, helping prospective clients develop proposal solicitations, and advising existing clients about PBMs' value. They have provided useful insights for benefit designs, but they also have adopted what PBMs might label a "guarantee mania" in contracts, wherein if some aspect of performance can be measured, there should be savings guarantees to incentivize PBMs to perform at this level.

Health benefits consultants' dual role as designer and evaluator might be viewed as a conflict of interest. As noted in the "PBM Clients" section, consultants generating requests for proposals and then evaluating performance relative to these proposals can yield a perverse incentive to foster "churning" in the PBM industry (where new contracts are developed, assessed, and decided on). Certainly, the PBM consultant business has been ripe for entrepreneurial activities.

Patients and caregivers

Patients and the people who care for them (nurses, family members, agents) also are potentially affected by PBMs in ways other than the obvious facilitation of receiving a drug benefit. Confidentiality issues are a potential concern, as for example when data on patient population drug use are sold or analyzed outside of the realm of providing the benefit (e.g., for use by manufacturers for marketing surveillance and use patterns). Patients also have "freedom to know" if interventions related to their drug use are being made without their consent or full knowledge of all the parameters (e.g., in physician contact for therapeutic interchange where there is financial benefit for the PBM or other parties). These are complex ethical issues with potential deleterious impacts on patients.

There also can be potential access issues for patients. Access to a convenient or desired pharmacy can be compromised in restricted networks. Access to needed drug therapies can be compromised when closed formularies are employed by PBMs. Unanswered questions remain about the impact of therapeutic interchange programs on patient health outcomes.

PBMs potentially offer an opportunity to apply rational, cost-effective decision-making to the prescribing and use of prescription drugs. PBMs' application of innovative behavioral change interventions, their commitment to development and refinement of information technology systems, their stimulation of price competition among drugs in the same therapeutic class -- all of these activities argue for a potentially beneficial role of PBMs on the quality and economy of drug prescribing and use. PBMs may facilitate the

incorporation of the pharmacy benefit and the pharmacist as integral components of the health care delivery system, thereby enhancing coordination of care.

Prescribers

Prescribers are affected when PBM drug use management techniques intervene in their practice. Calls by pharmacists (in retail or PBM settings), patients, or others for prescribing changes to meet PBM requirements are potential time impositions. These impositions potentially are balanced by patient care enhancements derived from improved monitoring or clinical input by PBM staff or agents. Often, the PBM can provide a useful oversight function, by virtue of the datasets they maintain and drug use criteria and algorithms they employ. What are the results of therapeutic interchange and other PBM programs to encourage formulary compliance and high-quality prescribing? Are physicians altering long-term prescribing patterns for their PBM patients (and non-PBM patients)? Until these data are known, the full impact of PBMs on prescribers is difficult to assess.

An unresolved issue is the effect of PBM programs, such as prior authorization, on physician prescribing. If prescribers learn that a drug is on a prior authorization list, to what extent do they avoid prescribing this drug even when they believe it is the optimal therapy? PBMs can measure the number of denials of prior authorization, but the total impact on prescribing of prior authorization programs and other formulary-related restrictions is difficult to measure.

PBM clients

Undoubtedly, PBMs have an impact on their clients. Information asymmetry is a distinct possibility between PBMs and their clients. The majority of clients are relatively inexperienced with evaluating the quality or cost of a drug benefit program, and the success a PBM might promote. To date, it remains difficult to assess the savings and effectiveness of PBMs, both inside and outside the PBM industry. Questions of how to gauge quality, economy, and outcomes are common, and purchasers do not know where to look for answers. This problem likely will continue for some time.

VIII. Conclusions and Policy Recommendations

Research Agenda

Barriers to Future Research

There are five major barriers to the conduct of future work on PBMs: the proprietary nature of some of the most important data elements; the inaccessibility of privately-conducted surveys and data sources; the difficulty in determining a meaningful baseline against which PBM cost savings can be projected; challenges involved in conducting rigorous, well-controlled studies; and the absence of claims data from other medical services.

As noted throughout this report, data bearing on rebate levels and strategies, PBM cost savings, and quality of care study results were considered proprietary by the PBMs and were not made available to the research team. In a few cases, information was kept confidential even when it was in the public domain (e.g., names of clients). One solution in the public sector is to build in contractual language and statutory requirements that Medicaid and other government funded/sponsored programs receive the cost and quality data on their programs in a timely fashion.

Second, while there are several publicly available studies (e.g., GAO reports[28]), many existing studies on the PBM industry are proprietary, available at a high price, or conducted by the PBMs themselves. Consulting firms have conducted studies in important areas such as the impact of PBMs on cost savings, disease management programs, and client satisfaction. Abbreviated results of these surveys are reported in the trade press; however, a more rigorous examination of the study sample, research design, and survey questions necessitates the purchase of the studies, at prices of several thousand dollars or more.

A third barrier to the conduct of PBM-related research is the difficulty in determining a meaningful baseline against which quality, cost savings, and cost impacts of PBMs can be measured. (The "baseline" relates to the starting point from which measurements are taken of change or impact due to PBMs and drug use management efforts.) Few, if any, potential clients or comparative populations are at the same baseline in terms of drug use and cost levels, and structure of the existing drug program and benefit. Consequently, estimates of cost or quality changes in any given program related to PBM activities cannot be extended or extrapolated to other programs.

A fourth barrier to assessing the impact of PBM activities relates to issues of causality and control. Factors affecting drug and health service use are numerous and

---

[28] See the following GAO reports: *Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers* (GAO/HEHS-96-45) or *Blue Cross FEHBP Pharmacy Benefits* (GAO/HEHS-96-182R).

complex; thus, attempting to control for all variables and attribute causation to the research variables is difficult, especially when the intervention is a "natural experiment." Randomized controlled trial designs are generall not possible for measuring the effects of natural experiments like the emergence of PBMs into the health care system. Further, alternative non-experimental design studies are often inadequate for obtaining valid and reliable measures of program impacts. The statistical power and validity of strong, quasi-experimental designs, including interrupted time-series analyses, can be used to evaluate impacts of health programs such as PBMs. The increased use of these stronger time-series designs is important because they can control for secular changes in estimates of program impact on cost, quality, and outcomes. During the past decade, some researchers have pioneered the use of these stronger time-series designs to examine the effects of cost-containment prescription drug policies on costs, quality and outcomes of health care (Soumerai et al. 1994; Ross-Degnan et al. 1993; Soumerai et al. 1991; Soumerai et al. 1987).

A fifth barrier is the absence of medical claims data. Any attempt to examine outcomes would require examination of the impact of drug use on the utilization and cost of other health care services. Not all MCOs appear interested in submitting medical claims data to PBMs for these purposes, and capitated plans may not have specific cost-per-service data. Similarly, as more Medicaid recipients enroll in managed care plans, public records formerly accessible to researchers through the Medicaid fee-for-service system are now being lost. Specifically, encounter data, which permit patient-level analyses, are being substituted by aggregate measures such as the HEDIS indices. Medicaid and other government programs should require the maintenance of a core group of data elements on populations subcontracting with MCOs with contracts to PBMs.

Description of Second-Generation Studies

A number of specific research questions emerged from the current study. These are presented below.

1. PBM-pharmacist risk-sharing arrangements. What impact does PBM and pharmacist risk sharing have on quality and cost of care, compared to Medicaid fee-for-service or a PBM-managed fee-for-service program?

2. Comparative studies of different formulary models. What are the effects of a closed formulary versus a managed, open formulary on cost and quality?

3. Examination of quality-of-care indicators. How can HEDIS drug-related quality measures be better supported by PBMs working with MCOs? How will these measures be used for internal and external quality assurance? Are these indicators valid measures of quality, that is, are they predictive of clinical outcomes?

4. Systematic study of the number of covered lives served by PBMs.

Calculating the actual number of PBM covered lives would enable an accurate assessment of their market penetration. As noted in the overview, obtaining accurate information on the total number of PBM covered lives is difficult because one person may be covered by several PBMs providing different services (e.g., mail order services and retail services). Double-counting inflates the total number of covered lives reported by PBMs (see Typology section). Further, PBMs tend to exaggerate the number of covered lives by counting those enrollees who receive only partial packages of PBM services. For example, in 1994, Pharmacy Gold, a PBM specializing in formulary management, reported 18 million covered lives, with 1 million full-service PBM customers, and 17 million covered lives enrolled only in the formulary management program. It is important to assess systematically, for each PBM, what proportion of its covered lives are receiving the full array of PBM services, which at a minimum, includes claims processing/ adjudication; network selection; formulary development and management; and rebate negotiations.

5. Longitudinal study of PBMs' impact on cost, quality and outcomes as experienced by PBM clients. Such studies could include insurers, managed care organizations, Medicare, Medicaid, and the Federal Employees Health Benefits Program. The latter two public purchasers might be the most willing to participate in such a study. Specifically, the FEHBP's PBM would be a valuable participant in the study because it has access to medical and drug claims data and uses a mail order option and retail pharmacy network between which to draw comparisons.

6. Comparative analyses of a PBM "carve in" versus "carve outs" on coordination of care and outcomes. Some analysts argue that the "disconnect" between the pharmaceutical and medical data bases in PBMs makes the realization of disease management objectives problematic, i.e., ultimately, who is accountable for the health of the enrolled population and for seeing that enrollees receive optimal health care when these responsibilities are divided? Given the controversy, and the absence of data to validate or negate these views, a research study would offer comparative analyses of the quality, costs, and outcomes of care in different pharmacy benefit management arrangements: (1) "carved-in" PBMs (e.g., when the entire pharmacy benefit is managed by the health plan as in Kaiser Permanente, a group model HMO, when a Medicaid managed care organization manages the pharmacy benefit "in-house," or when the clinical component of the drug benefit is managed by an insurer which subcontracts with a claims processing vendor); (2) "traditional" carved-out PBM (i.e., where the pharmacy benefit is subcontracted to the PBM by the employer, insurer, or managed care organization and the PBM performs typical functions, such as claims processing, network management, formulary development, and rebate negotiations); and (3) "leading edge" carved-out PBM (i.e., where the PBM is re-engineering the pharmacy benefit by implementation and rigorous evaluation of disease management programs, performing cost-effectiveness analyses of cost-cutting and quality-of-care initiatives, and integrating pharmacy and medical data to permit meaningful outcomes studies).

7. Impact of vertically integrated PBMs. Do access, quality, costs and outcomes of PBMs differ between vertically-integrated PBMs and those that are not vertically-integrated?

8. Comparisons among different types of carve-out programs. PBMs represent only one kind of carve out being pursued by managed care organizations. Historically, mental health services have been carved out, and more recently, several health maintenance organizations have subcontracted oncology care to a cancer center.[29] What are the similarities and differences in these respective carve-outs? Are there lessons learned from one sector that can be extrapolated to another? More fundamentally, does carving out a limited benefit like mental health result in greater fragmentation of health care delivery and a lack of aligned incentives? How can coordinated health care best be achieved under a system of carve-outs?

9. Comparisons among different kinds of capitation arrangements. The growth area for PBMs is in the managed care sector. Some health plans are capitating physician groups for drugs, whereas others are moving toward a global capitation rate inclusive of all medical, pharmaceutical, and inpatient services. An interesting second-generation study would be a comparison of clinical and economic outcomes in the two different capitated systems. One hypothesis would be that in physician groups in which there is a separate drug risk pool there would be lower drug costs and higher overall health care costs than in physician groups in which there was a global capitation rate.

10. Impact of physician incentive programs. There are multiple ways in which physicians are motivated through financial incentives to prescribe in a cost effective manner. One is through the creation of drug risk pools in managed care organizations. Another is the use of "withholds" or "bonuses" if physicians achieve targeted levels of formulary compliance and generic prescribing rates. Another is by managed care organizations sharing their manufacturer rebates with their physician groups (typically, IPAs). Still another is physicians as employees of a PBM with an equity interest in the company. This is the Caremark model in which a PBM owns medical groups, a model which maximizes the potential to align medical, pharmacy, and inpatient incentives and data. A research question for future study would involve a comparison of these different physician incentive programs.

11. Extent and effects of PBM consolidation. There has been recent consolidation and alliances within the PBM industry (including older PBMs acquiring PBM startup companies). What is the effect of these efforts on PBM growth and outcomes? Will there continue to be consolidation of PBMs, similar consolidation efforts in other sectors of the medical market?

---

[29] For more information, see "Salick is Pioneering Selling Cancer Treatment to HMOs," by Rhonda Rundle, in the *Wall Street Journal*, August 12, 1996.

12. Policy research. What is the role of the government and public policy makers in the PBM industry? Should government play a role in development of standardized data elements and the issuance of PBM "report cards"?

13. Mail order compared to retail pharmacy. Rigorous, systematic studies are needed comparing costs and quality of mail service and retail pharmacy providers.

Action Agenda

The following section offers an "action agenda" that presents questions purchasers might wish to ask PBMs to better understand prospective contracts. This section also offers strategies and recommendations to various stakeholder groups -- primarily different types of purchasers (current and potential) of PBM services. In particular, the role of PBMs with regard to the Medicaid, Medicare, and other government programs is discussed.

Questions for Purchasers of PBM Services

Formulary and Drug Utilization Issues

- What is the generic dispensing rate (e.g., percent of all prescriptions, percent of substitutable prescriptions, percent of prescriptions where pharmacists perform substitution)? Generic drugs are less expensive than branded generics or sole source drugs (drugs that have no generic) because they are not protected by patent. PBMs use a variety of financial incentives (e.g., lower co-payments for generics, generic substitution) to encourage generic drug dispensing. While the use of sole source drugs may provide a greater rebate, the net drug cost may be greater.

- What are the mechanisms used to direct prescription drug use towards formulary products? What is the rate of use of preferred formulary drugs?

- Are the P&T committee members independent of the PBM? (Committee members should not be employees or agents of the PBM or parent company, nor should they have financial interest in the PBM or parent company, except for ownership of a small amount of stock, e.g., less than 1/10 of 1 percent).

- Is the type of formulary (open, closed, managed) tied to client payment structure, e.g., does the PBM require a closed formulary for an client with a capitated payment arrangement?

- What percent of claims result in P-DUR alerts? What are the most common alerts? What percent of alerts result in a responsive action by the pharmacist? What is the process for reviewing P-DUR criteria to eliminate criteria with high rates of false positives? How frequently does this process occur?

- Describe the interaction which occurs between the pharmacist and patient at point-of-sale.

- Describe PBM interventions at the physician level. What are the PBM's goals regarding physician prescribing practices? How is the success of these interventions evaluated?

- Ask for samples of management reports and DUR reports. Is the reporting system available on-line? Can the PBM produce client-specific reports? Custom-designed reports?

- Clients should be extremely familiar with the PBM contract. Stipulate specific expectations about administrative and clinical services, such as DUR and reporting. Specify length of time for intervention and evaluation after problems are identified.

- What types of performance guarantees are offered in the contract?

Pharmacy network

- What is the process for selection of pharmacies for participation in the network(s)? Access should be defined by the distance of the pharmacy from members' residences, not in terms of the absolute number of pharmacies in the network.

- What are the terms of pharmacy payment in the broad network? In the restricted network?

- How are pharmacies selected for audit? Describe audit procedures. What is the result of poor performance as detected by a pharmacy audit?

- Is the mail order service provided in-house or by an outside vendor? Are the retail pharmacy and mail order claims databases integrated? (Describe the manner in which they are integrated.)

Rebates and the Sale of Data

- Describe your methodology for distributing rebate dollars to your clients. Are calculations based upon averages of all your accounts, or on a client-by-client basis?

- What percent of rebate dollars do clients receive? How is the rebate calculated? The PBM may receive fees from pharmaceutical manufacturers for the sale of drug utilization data but does not share this revenue with clients. However, the amount the manufacturer pays for data may affect the amount it pays in rebates, which affects the amount of rebate dollars the client receives.

- In terms of the sale of drug utilization data by PBMs to drug manufacturers, who owns the data -- the client or PBM? To what use will it be put? Does the PBM client share in these revenues? PBM contracts should stipulate specifically the terms of ownership and sale of data.

Charges, Costs, and Cost Savings

- What is the PBM's administrative per-claim fees? What services are included in this base rate? What services are charged separately?

- Will the PBM accept capitated or risk-sharing arrangements?

- Does the PBM accept different reimbursement rates for different subgroups of covered lives or only have one universal rate? (e.g., client willing to pay higher PMPM for Medicare risk product than for AFDC risk product?)

- Describe the PBM's MAC program. How are drugs selected? How often is the MAC list updated?

- Ask for the average cost per prescription rather than per-member-per-month (PMPM). What is the average cost per prescription (adjusted for 30-day supplies), net of any rebates and co-payments for all drugs? for the ten most costly drug categories? While PMPM costs may also be a useful measure, PMPM is greatly influenced by differences in case mix of the population (e.g., the elderly use more drugs compared to AFDC recipients). Average cost per prescription reflects the use of generic or preferred drugs and is less influenced by differences in case mix.

- Do PBMs' cost savings estimates take into account secular changes such as increased number of generic drugs on the market, or increased number of drugs switched from prescription to non-prescription status?

Client Satisfaction with Service

- Ask the PBM for the names of contact persons among its clients. Ask for the name of a contact person for clients who recently changed to another PBM or who brought the PBM service in-house

- What is the response time for calls from plan sponsors and beneficiaries to PBM "help" desk? Is this phone line a toll-free (800) number?

Summary and Conclusion

Reviewing the literature and interviewing PBM executives and various stakeholders revealed the world of PBMs is complex and dynamic. PBMs have some critically important capabilities and have a track record of success in several areas of drug program administration. They use many techniques to manage drug programs, some targeted towards patients, some towards pharmacists, and some toward physicians. Although PBMs have grown, in terms of the covered lives they represent, data and/or evidence on the cost and quality of PBM activities are not always available, clear, or conclusive.

PBMs have been successful in establishing and managing pharmacy panels and in extracting competitive prices from pharmacy providers. They also have negotiated price concessions from manufacturers in the form of rebates for drugs dispensed to PBM covered beneficiaries, thus extending their influence on components of the cost of drug programs throughout the supply side of the channel of distribution. Historically, rebates from manufacturers have been based on volume, but increasingly are linked to PBM influenced changes in market share. Compared to OBRA '90 rebates for Medicaid programs, the level of rebates and proportion of products rebated in PBM programs are lower. The drug use management techniques employed by PBMs often are oriented toward effecting market share changes and the corresponding rebates that ensue.

Claims processing is a core capability of PBMs, and their expertise with this function has led to the development of sophisticated data and information systems. In particular, PBMs have created point-of-sale P-DUR systems, establishing criteria and efforts to help ensure effective and efficient drug use. These efforts are not without challenges such as false positives and difficulty in follow-up evaluations of denied claims to assure adverse outcomes did not result, or that subsequent delayed use or transference to an alternate drug did not occur. Less emphasis is placed on R-DUR, perhaps because it is less proactive and thus believed not as important or potentially successful in influencing drug use. Although claims processing and data systems are areas of strength, PBMs have had only limited success in linking pharmacy data with medical and other health care utilization claims data. The full potential of disease management programs cannot be realized until these linkages occur. State Medicaid programs have linked drug and other medical data through their management information system.

Mail service appears to be a demanded function, thus, it is a typical component of PBM service offerings, although the emphasis placed on mailed prescriptions varies among PBMs. There has been a trend for PBMs to bring this function "in house," in an effort to control mail service activities, such as drug product selection, and to avoid the "middleman."

Drug use management techniques employed by PBMs include the DUR activities mentioned previously, formularies and activities related to formularies (e.g., prior authorization, generic substitution and therapeutic interchange), and disease management programs. As a result of client requests, most PBM formularies are "open" or "managed," however MCO clients often have more restrictive or aggressively managed formularies, and the general trend is moving toward using more restrictive formularies. Since disease management is a relatively new phenomenon, it has not been widely adopted by clients and only small proportions of PBM covered lives are participating in disease management programs.

The capabilities and characteristics of PBMs lead to questions about the role of PBMs for Medicaid and other government programs and the impact of PBMs on the larger pharmaceutical market. Although Medicaid currently reflects a potential market, PBMs have not established direct contracting arrangements to manage any state drug program, in part because state pharmacy consultants question whether they will achieve the same rebates levels that they now experience under OBRA 90. Compared to many state Medicaid programs, PBMs may have enhanced abilities to achieve market rates in pharmacy payments and better data and information systems, particularly in P-DUR programs. However, there are aspects of Medicaid programs and populations that are unique and challenging, including the inability to use sizable patient financial incentives to influence drug use behaviors (e.g., differential co-payments for preferred formulary drugs), non-continuous eligibility and lack of a stable address that can cause problems for mail service dispensing, and differences in Medicaid populations relative to typical PBM covered populations (such as aged and disabled recipients with intense medical needs, and long-term care residents with a different distribution system).

PBMs have been involved with Medicaid and Medicare programs indirectly, through state managed care initiatives that have resulted in Medicaid or Medicare beneficiaries enrolling in MCOs. Additionally, Medicare beneficiaries with supplemental insurance policies may have their drug benefit managed by a PBM. If Medicare is expanded to include outpatient drug benefits, there may be a potential role for PBMs in administering and managing the benefit, conceivably giving them a powerful market role. The magnitude of a potential drug program under Medicare represents a considerable challenge for the PBM industry, either for an individual firm or several firms working in combination or consortially to manage the drug benefit.

Through subcontracts with MCOs, PBM management of drug benefits for Medicaid recipients likely will increase as Medicaid continues to move from fee-for-

service to managed care. The Medicaid program needs to develop programs to measure and monitor the quality of drug therapy delivered by managed care organizations and to create mechanisms to ensure timely feedback of results.

Implications of PBMs on the larger pharmaceutical marketplace fall primarily on pharmacies and pharmaceutical manufacturers since they are most directly affected by PBM policies and drug use management techniques. In both markets, PBMs affect revenue streams, with potential long range effects of industry consolidation and reduced access or quality.

The overall impact of PBMs on cost , quality, and patient outcomes requires more intensive and systematic study. Questions remain as to whether there are incremental enhancements in economy, efficiency, and quality associated with PBMs, and if so, at what cost? Several barriers to conducting future research on PBMs and answering these questions include:

- the proprietary nature of important data elements necessary for assessments;

- difficulty in defining meaningful baseline measurements against which cost savings, cost impacts, and quality can be measured;

- challenges in research design to control for numerous potentially causal factors in complex systems;

- difficulty in linking pharmacy claims data with data from other medical services.

To date, it appears that the PBM industry has not given states compelling reasons to establish direct contracts for managing their Medicaid drug programs. If or when more evidence becomes available about the influence PBMs have on cost and quality in drug programs, states will have more information with which to decide. The burden of proof lies with the PBM industry; the strength of their evidence will influence the path states will take. This proof may not come easily since state Medicaid officials have considerable experience with their existing programs, and thus gauge the potential that a PBM may or may not represent with a critical eye.

Glossary of Terms

Algorithm: The step-by-step rules for applying the criteria to the data to arrive at the exception.

Any Willing Provider: Legislation compelling insurers to sign a participation agreement with any provider (such as pharmacy or physician) that agrees to abide by the same terms of the contract and to accept the same payment level as other providers.

Average Manufacturer Price (AMP): The average price paid by wholesalers for products distributed to the retail class of trade.

Average Wholesale Price (AWP): The composite wholesale prices assigned by the drug manufacturer and listed in either the Red or Blue Books.

Best Price: Lowest price paid by any purchaser (exclusive of depot prices and single-award contract prices defined by any federal agency).

Capitation Fee: A reimbursement system where the providers of health care receive a fixed payment for every patient served regardless of how many services are provided.

Carve out: Exempting a service or population from managed care program or insurance plan and reimbursing through a separate means. For example, Medicaid may exclude pharmaceuticals from a managed care contract, paying for pharmaceuticals on a fee-for-service basis.

Carve in: Including a service or population in a managed care program or insurance plan that was previously reimbursed on a separate basis.

Co-insurance: A cost-sharing requirement under a health care policy which provides that the insured will assume a portion or percentage of the cost of covered service.

Co-payment: The portion of health care costs a beneficiary is expected to pay. Unlike co-insurance, co-payment is a fixed cost.

Criteria: Predetermined elements of drug use against which aspects of quality, medical necessity and appropriateness of drug use may be compared.

Disease management: A comprehensive, integrated approach to care and reimbursement based on the natural course of a disease, with treatment designed to address the illness by maximizing the effectiveness and efficiency of care delivery. The emphasis is on preventing disease and/or managing it aggressively where intervention will have the greatest impact. Drug disease management focuses on chronic, high-cost medical conditions where pharmaceuticals play a critically important treatment role, such as diabetes, asthma and depression.

Estimated Acquisition Cost (EAC): Estimated cost based on price generally and currently paid by providers for a drug in the package size most commonly purchased.

Firewall: FTC requirement that PBMs owned by manufacturers must prevent the flow of certain information between PBM and parent company and vice versa; for example, the parent company is prevented from obtaining information pricing and bid features submitted by competitors to the PBM.

Formulary: A list of drugs approved for use.

An *open* formulary implies coverage for almost all drugs; the patient's payment is not based on a drug's formulary status.

A *closed* formulary is a limited list of drugs approved for use. Nonformulary drugs are not covered by the plan.

A *managed* formulary offers the patient financial incentives when a formulary or preferred drug is dispensed, e.g., a lower co-pay or lower percent co-insurance. Some PBMs have developed lists of preferred drugs which are subsets of their formularies. As the preferred list of drugs is "enforced" to greater degree, the formulary becomes increasingly managed. The formulary may be "enforced" through a variety of interventions designed to affect changes in prescribing and dispensing behavior.

Generic Substitution/Interchange: Switching from a brand-name drug to a chemically-equivalent, generic alternative.

Maximum Allowable Cost (MAC): Maximum cost paid for certain multi-source drugs (generic drugs).

Network: Arrangement where providers contract with payers or managed care organization to provide services for patients enrolled in health plan.

Prior Authorization: The approval a provider must obtain from an insurer or other entity before performing certain procedures, or using certain medical products or drugs, in order for the service to be covered by the plan.

Prospective Drug Utilization Review (P-DUR): DUR which occurs before the medication is dispensed by the pharmacist. P-DUR provides an opportunity for the pharmacist to modify the patient's therapy, if warranted. P-DUR is frequently referred to as concurrent DUR (C-DUR).

Retrospective Drug Utilization Review (R-DUR): DUR which occurs after the medication has been dispensed.

Therapeutic Interchange: A practice entailing a pharmacist contacting a physician for approval for a change in prescription, such as from a nonformulary to a formulary drug, when the new drug is chemically different from the originally prescribed drug but has a comparable therapeutic effect.

Therapeutic Substitution: A practice entailing a pharmacist substituting a drug felt to be therapeutically equivalent to the drug prescribed without receiving authorization from the physician.

Waivers (Section 1115 or 1915(b)): Section 1115 of the Social Security Act grants the Secretary of Health and Human Services broad authority to waive certain laws relating to Medicaid for the purpose of conducting pilot, experimental or demonstration projects. Section 1115 demonstration waivers allow states to change provisions of their Medicaid program, including: eligibility requirements, the scope of services available, the freedom to chose a provider, a provider's choice to participate in a plan, the method of reimbursing providers, and the statewide application of the program.

Section 1915(b) freedom-of-choice waivers allow states to require Medicaid recipients to enroll in HMOs or other managed care plans in an effort to control costs. The waivers allow states to: implement a primary care case-management system; require Medicaid recipients to choose from a number of competing health plans; provide additional benefits in exchange for savings resulting from which beneficiaries can receive non-emergency treatment.

REFERENCES

A. Foster Higgins: *National survey of employe -sponsored health plans*. 1995.

Adams KE, N Gavin, DH Kreling: *Assessment of adequacy of reimbursement rates to pharmacies and the impact on the access to medications and pharmacy services by medicaid recipients*. Final Report to HCFA, Contract No. 500-92-0024. August 25, 1993.

American College of Physicians: Therapeutic substitution and formulary systems, a position paper. *Annals of Internal Medicine* July 1990;113(2):160-163.

American Druggist: PCS pilots third M.D. link. January 1996;213(1):1.

American Pharmaceutical Association Foundation: *Medicaid DUR programs, 1993* (Washington, DC) August 1995.

Anis AH: Substitution laws, insurance coverage, and generic drug use. *Medical Care* March 1994;32(3):240-256.

Beavers N: PBMs partner to boost generic usage. *American Druggist* December 1995;212(8):18, 21.

Borzo G: Drug firms expand into patient care. *American Medical News* June 1996;39(24):1, 7, 8.

Brian EW, SF Gibbons: California's Medi-Cal copayment experiment. *Medical Care* 1974;12(Supplement):1-56.

Browning ES, TM Burton: Lilly's PCS may take write-down. *Wall Street Journal* July 30, 1996.

Business & Health, Special Report 1995: Pharmacy risk-sharing promotes savings. Vol. 13(3) Supplement B:18-21.

Business Insurance: Directory of Pharmacy Benefit Management Companies. April 1995;29(14):18-23+.

CibaGeneva Pharmacy Benefit Report, 1996 Trends & Forecasts. Emron, Inc., 1996.

Ciba Pharmacy Benefit Report: Emron, Inc., 1995.

Ciba Pharmacy Benefit Report: HMO Facts & Figures, 1994 Year-End Edition. Summit, NJ: Ciba Geigy, 1994.

Code Federal Regulation 42 CFR 456, 1996.

Collins TM, DA Mott, WE Bigelow, DR Zimmerman: A controlled letter intervention to change prescribing behavior: results of a dual-targeted trial. *Health Services Research* (in press, 1996).

Conlan MF: Medco suit hits rite aid. *Drug Topics* March 1996;145(5):21.

Conlan MF: Switch glitch: states slap Merck-Medco marketing tactics. *Drug Topics* November 1995;139(22):78.

Dowell JS, D Snadden, FA Dunbar: Changing to generic formulary: how one fundholding practice reduced prescribing costs. *British Medical Journal* February 1995;310:505-508.

Drug Topics: DPS buys mail-order pharmacy. March 1995;139(5):7.

Drug Topics: Pharmacy gold: formulary manager and PBM. September 1994;138(7):78.

Epstein D: Why some brands are favored over generics in formularies. *Drug Topics* 1995 (Supplement)139:21s-22s.

Etheredge L: Pharmacy benefit management: the right Rx? Health Insurance Reform Project, George Washington University. Funded by the Robert Wood Johnson Foundation. April 1995.

Fitzer-Schiller G: Drug companies without PBMs face troubled times. *Reuters, Limited* May 19, 1994.

Freudenheim M: Regulators and Lilly in accord. *The New York Times* October 26, 1994, Section D, page 1.

Freudenheim M: A shift in the power of pharmaceuticals. *The New York Times* May 9, 1994, Section D, page 1.

Gebhart F: Medco expanding its mail-order diabetes management program. *Drug Topics* August 1995;139(16):59-60.

Gebhart F: Rebates for drug switch under fire in California. *Drug Topics* July 1995;139(13):68, 70.

Gemignani J: PBMs: why this exponential growth? *Business & Health* March 1996;14(3):53-54.

General Accounting Office: *Blue Cross FEHBP Pharmacy Benefits* GAO/HEHS-96-182R, Washington, DC, 1996.

General Accounting Office: *Pharmacy benefit managers: early results on ventures with drug manufacturers.* GAO/HEHS-96-45, Washington, DC, 1995.

General Accounting Office: *Prescription drugs: automated prospective review systems offer potential benefits for Medicaid.* GAO/AIMD-94-130, Washington, DC, 1994.

General Accounting Office: *Prescription Drugs and Medicaid. Automated review systems can help promote safety, save money.*GAO/AIMD-96-72, Washington, DC, 1996.

George J: Pharmaceutical fields are learning new rules. *Philadelphia Business Journal* July 1994;13(19):1.

Gibaldi M: Vertical integration: the drug industry and prescription benefits managers. *Pharmacotherapy* 1995;15(3):265-271.

Grabowski HG, CD Mullins: Cost-effectiveness analysis and pharmacy benefit management companies. *Social Science and Medicine* 1997; Special issue on cost-effectiveness analysis in decisionmaking (forthcoming).

Groves RE: Therapeutic drug-use review for the Florida Medicaid program. *Am J Hosp Pharm* 1985;42:316-9.

Harris BL, A Stergachis, LD Ried: The effect of drug co-payments on utilization and cost for pharmaceuticals in a health maintenance organization. *Medical Care* October 1990;28(10):907-917.

Health Care Financing Administration: *Medicare and Medicaid Statistical Supplement.* February 1995.

Health Care Financing Administration: *State Medicaid Manual* Part 6- Payment for Services. October 1992.

Health Care Financing Review: Medicare and Medicaid Statistical Supplement. February 1995.

Horgan C, B Goody, H Batten, J Boren, D Knapp, S Schondelmeyer, A McKay, F Palumbo, L Goren: *Study to evaluate the use of mail service pharmacies.* HCFA Final Report, Grant #88-C98526/1-05, September 21, 1989.

Horn SD, PD Sharkey, DM Tracy, CE Horn, B James, F Goodwin: Intended and unintended consequences of HMO cost-containment strategies: results from the managed care outcomes project. *American Journal of Managed Care* March 1996;II(3):253-264.

Impact of the Medicaid Drug Rebate Program on Expenditures, Utilization and Access: Final Report to HCFA, Contract No. 500-92-0022. April, 1995.

Issues Answers: Drug utilization review. 1990;1(2):4-15.

Jackson R: Survey sees low HMO happiness with drugmaker plans. *Managed Pharmaceutical Report* April 1996;3(4):7-8.

Jang R: Medicaid formularies: a critical review of the literature. *Journal of Pharmaceutical Marketing and Management* Spring 1988;2(3):39-61.

Jay ED, EP Eynon, HS Javitz: The Medi-Cal therapeutic drug utilization review project: quarterly report and final analysis report. Menlo Park, CA: SRI International, 1991.

Keith MR, DM Cason, DK Helling: Antiulcer prescribing program in a state correctional system. *The Annals of Pharmacotherapy* June 1994;28(6):792-796.

Kotzan JA, JA McMillan, CA Jankel, AL Foster: Initial impact of a Medicaid prior authorization program for NSAID prescriptions. *Journal of Research in Pharmaceutical Economics* 1993;5(1):25-41.

Lawrence DB, CW Weart: HMO pharmacy directors' opinions of acquisition of pharmacy benefit management companies. *Am J Health-Syst Pharm* 1995;52:1547-9.

LeGrady D: The Nebraska Medicaid drug utilization review program *Nebr Med J* 1992;77(1):3-6.

Levit KR, HC Lazenby, L Sivarajan: Health care spending in 1994: slowest in decades. *Health Affairs* 1996;15(2):130-144.

Lipton HL, JA Bird: Drug utilization review in ambulatory settings: state of the science and directions for outcomes research. *Medical Care* 1993;31:1069-1082.

Lipton HL, JA Bird: Drug utilization review: State of the art from an academic perspective. *Clin Pharmacol Ther* 1991;50:616-619.

Managed Healthcare: Directory of pharmacy benefits management companies. May 1995;5(6):PBM 1-16.

Managed Healthcare: Directory of pharmacy benefits management companies. May 1996;6(6):PBM 1-16.

Managed Pharmaceutical Report: PCS program rewards pharmacists who use cost-effective drugs. June 1996:5-7.

Managed Pharmaceutical Report: Pilot DUR program finds potential savings of $1 per Rx claim. February 1995:8.

Managed Pharmaceutical Report: Prescription solutions launches formulary on Internet. July 1996:6.

Marion Merrell Dow Managed Care Digest: HMO Edition (Kansas City, MO: Marion Merrell Dow, 1994).

McCombs JS, MB Nichol: Pharmacy-enforced outpatient drug treatment protocols: a case study of Medi-Cal restrictions for Cefaclor. *Annals of Pharmacotherapy* February 1993;27(2):155-161.

McEachern S: PSAOs: fewer, but stronger. *Managed Care Pharmacy Practice* March/April 1995;33-36.

William M. Mercer, Inc.: 1995 national survey on advanced pharmacy benefits. Source: "Most firms pursuing disease management to control drug costs." *Managed Pharmaceutical Report* April 1996:10.

Muirhead G: Chain PBMs. *Drug Topics* July 1996;140(13):100, 103.

Muirhead G: Express scripts takes on pharmacy and medical data. *Drug Topics* June 1996;140(11):100-103.

Muirhead G: Inside academic detailing: where's community pharmacy? *Drug Topics* June 1996;140(11):104, 106.

Muirhead G: Paying pharmacists for enforcing formulary makes good sense. *Drug Topics* January 1995;139(2):32-33.

Muirhead G: Learning to live with formularies. *Drug Topics* February 1994;138(4):38-40, 43.

Muirhead G: Formulary management moves forward at pharmacy gold. *Drug Topics* October 1994;139(20):49, 53.

Naj AK: Merck's sales boosted net 13% in quarter. *Wall Street Journal*, July 19, 1996, B-3.

National Pharmaceutical Council: *Pharmaceutical benefits under state medical assistance programs.* Reston, VA, September, 1995.

Navarro R: Exportation of U.S. pharmacy benefit management companies to Canada. *Medical Interface* July 1995:72-74.

Nelson AA, CE Reeder, WM Dickson: The effect of a Medicaid drug copayment program on the utilization and cost of prescription services. *Medical Care* August 1984;22(8):724-736.

Newhouse JP, WE Manning, CN Morris, LL Orr, N Duan, EB Keeler, A Leibowitz, KH Marquis, MS Marquis, CE Phelps et al: Some interim results from a controlled trial of cost sharing in health insurance. *New England Journal of Medicine* December 1981;305(25):1501-1507.

Omnibus Budget Reconciliation Act, 1990: November 5, 1990 (Public Law 101-508).

The Pink Sheet: HHS IG auditing pharmaceutical pricing, impact of PBMs on patient quality of care; Kennedy/Kassebaum bill would add funds for IG fraud investigations. June 3, 1996:7-8.

Pollard JR, J Coster: Savings for Medicaid drug spending. *Health Affairs* Spring, 1991(10):196-206.

Reeder CE, AA Nelson: The differential impact of copayment on drug use in a Medicaid population. *Inquiry* Winter 1985;22(4):396-403.

Roemer MI, CE Hopkins, L Carr, F Gartside: Copayments for ambulatory care: penny-wise and pound foolish. *Medical Care* June 1975;13(6):457-466.

Ross-Degnan R, S Soumerai: HMO formularies and care costs. *Lancet* (correspondence) May 1996;347:1264.

Ross-Degnan R, SB Soumerai, EE Fortess, JH Gurwitz: Examing product risk in context: market withdrawal of Zomepirac as a case study. *Journal of the American Medical Association* October 1993;270(16):1937-1942.

Rothschild E: Lilly acquisition harms drug consumers (letter to the editor). *The New York Times* December 26, 1994;1:38.

Rucker TD: Drug utilization review: moving toward an effective and safe model. *Society and medication: conflicting signals for prescribers and patients*, JP Morgan and DV Kagan (eds.). Lexington, MA: Lexington Books, 1983:25-51.

Schulman KA, LE Rubenstein, DR Abernathy, DM Seils, DP Sulmasy: The effect of pharmaceutical benefits managers: is it being evaluated? *Annals of Internal Medicine* 1996;124 (10):906-913.

Slezak M: Mail-order changes its colors. *American Druggist* December 1995;212(8):22-24, 26, 30.

Slezak M: Maryland pharmacies say 'no' to Medco. *American Druggist* January 1996;213(1):20, 22.

Slezak M: Merck-Medco agrees to 'switch' practices. *American Druggist* December 1995;212(8):12.

Sloan A: Quick, get the Prozac; after this move, Eli Lilly's people may need it. *The Connecticut Law Tribune* August 8, 1994:27.

Smalley WE, MR Griffin, RL Fought, L Sullivan, and W Ray: Effect of a prior-authorization requirement on the use of nonsteroidal antiinflammatory drugs by Medicaid patients. *New England Journal of Medicine* 1995;332(24):1612-1617.

SMG Marketing Group, Inc.: *Pharmacy benefit managers database, 1995.* Source: "Changing PBM market grows 36% as firms focus on disease management." *Managed Pharmaceutical Report* January 1996;3(1):1.

Smith DG: The effects of copayments and generic substitution on the use and cost of prescription drugs. *Inquiry* Summer 1993;30(2):189-198.

Soumerai SB, HL Lipton: Computer-based drug-utilization review - risk, benefit, or boondoggle? *New England Journal of Medicine* 1995; 332:1641-1645.

Soumerai SB, D Ross-Degnan, EE Fortess, JA Abelson: A critical analysis of studies of state drug reimbursement policies: research in need of discipline. *The Milbank Quarterly* 1993;71(2):217-252.

Soumerai SB, D Ross-Degnan: Experience of state drug benefit programs. *Health Affairs* 1990;(3):36-54.

Soumerai SB, J Avorn, D Ross-Degnan, S Gortmaker: Payment restrictions for prescription drugs under Medicaid: effects on therapy, cost, and equity. *New England Journal of Medicine* August 1987;317(9):550-556.

Soumerai SB, TJ McLaughlin, D Ross-Degnan, CS Casteris, P Bollini: Effects of limiting Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *New England Journal of Medicine* September 1994;331(10):650-655.

Soumerai SB, D Ross-Degnan, J Avorn, TJ McLaughlin, I Choodnovsky: Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. *New England Journal of Medicine* October 1991;324(15):1072-1077.

Taniguchi R: Pharmacy benefit management companies. *Am J Health-Syst Pharm* September 1995;52:1915-1917.

Tanouye E, G Anders: Drug industry takeovers mean more cost-cutting, less research spending. *Wall Street Journal* February 1, 1995.

Tanouye E: Merck's Medco unit moves 'on track' chairman Gilmartin assures analysts. *Wall Street Journal* December 13, 1995.

Tanouye E: Prescription drugs prices are rising, defying predictions of inflation's demise. *Wall Street Journal* February 15, 1996.

Ukens C: Pharmacists fear some forced substitution, study shows. *Drug Topics* January 1995;139(1):24.

U.S. Department of Health and Human Services:*Guidelines for estimating the impact of Medicaid DUR* (Baltimore, MD: HCFA Medicaid Bureau, Contract # 500-93-0032). August 1994.

U.S. Department of Health and Human Services: *Impact of Medicaid drug rebate program, extramural research report* (Baltimore, MD: HCFA, Office of Research and Demonstration, Contract # 500-92-0022). August 1995.

VA Health Care: Opportunities for service delivery efficiencies within existing resources (Letter Report, 07/25/96, GAO/HEHS-96-121).

Walser BL: Pharmaceutical cost containment and quality assurance: trends in outpatient review programs and pharmaceutical benefits management. Basel, Switzerland: Hoffmann-LaRoche, 1994.

Washington State Department of Social and Health Services: *Report to State of Washington Department of Social and Health Services, Medical Assistance Administration for Selective Contracting*, William M. Mercer, Inc., December 1994.

Weekly Pharmacy Reports - The Green Sheet: Express scripts generates 55 percent switch rate in H2 antagonist class for 55 percent savings. January 1996;45(4):4.

Weekly Pharmacy Reports - The Green Sheet: Mail order branded scripts cost AWP-13%. November 1995;44(45):4.

Weekly Pharmacy Reports - The Green Sheet: Maryland State employees pharmacy contract bidding will be reopened. January 1996;45(1):3.

Weekly Pharmacy Reports - The Green Sheet: Medco mail-service interventions brand-to-brand switches have 51 percent success rate. December 1995;44(51):2.

Weekly Pharmacy Reports - The Green Sheet: PCS pharmacists will be counter-detailing. June 1996;45(23):1.

Weekly Pharmacy Reports - The Green Sheet: Franklin electronic formulary for N.J. plan reduces drug spending $1,275/month. March 1996;45(11):4.

Woolsey C: Any adverse effects? drug industry mergers invite more scrutiny of plan costs. *Business Insurance* July 18, 1994:1.

Yakabowich MR, G Keeley, PR Montgomery: Impact of a formulary on personal care homes in Manitoba. *Canadian Medical Association Journal* May 1994;150(10):1601-1607.

Zimmerman DR, TM Collins, EE Lipowski, F Sainfort: Evaluation of a DUR intervention: a case study of histamine antagonists. *Inquiry* Spring 1994;31:89-101.

Appendix A
PBM Interview Protocol

I. PBM Background Information

A. Background

1. Year Founded:

2. Corporate Status
   (a) publicly traded
   (b) privately traded
   (c) wholly-owned subsidiary
   (d) privately, closely held

3. Ownership Status
   (a) pharmaceutical mfg.
   (b) insurance company
   (c) independent pharmacies
   (d) other benefit management company
   (e) division/section of insurance company
   (f) division/section of managed care provider
   (g) other

B. History

4. Describe the history/evolution of your company. (e.g. What was your ownership/strategic alliance when founded? How has ownership and/or corporate status changed since origin? etc.)

C. Size and Scope

5. (a) What were your gross sales (PBM) during the last fiscal year?

   (b) How many prescriptions (total) were managed?

   (c) How many covered lives?

   -- Total covered lives?
   -- Mail Order covered lives?

   (c) Describe the growth you have experienced over the past two years in the

number of covered lives.

(d) What percentage of your covered lives are represented by the following client groups:

(i) employer groups? (are these all self-insured?)
(ii) insurance companies?
(iii) HMOs or other MCOs?
(iv) government-sponsored plans (Medicare & Medicaid enrollees)?
(v) other?

(e) How many clients do you serve?

How many separate client contracts do you have?

(f) Describe/characterize your major clients.

What proportion of your business is to national, regional, local clients? *(approximate % breakdown)*

(g) How many contracts do you have with clients who serve Medicaid patients?

How many Medicaid covered lives?

What the names and locations of some of your largest MCO clients with Medicaid enrollees?

D. Services Used -- Typical, Low and High

As a quick overview, could you list the services you offer that clients use? (e.g. claims processing, formulary, mail order, disease management, MIS support (utilization and cost reports), provider education--academic detailing, newsletters, development of best practice guidelines, etc.)

What percentage of your members use these services?

(a) Describe the "typical" bundle of services a "standard" client would purchase. Describe a "low" and a "high" user's service bundle, relative to this "typical" client.

(b) Approximately what proportion of your clients are "typical", "low", and "high"

service users?

(c) Are clients required to purchase a minimum set of services?

If so, what services are included in the minimum set?

II. Specific Services Descriptions

A. Formularies and Drug Coverage Parameters

1. **Formularies -- Type** (Open/Closed and Standard/Customized)

(a) What percentage (or about what proportion -- **most, many, some, few, none**) of your covered lives (clients) use a:

i. nonrestrictive formulary (i.e., no limits or constraints on drugs available or prescribed)?

ii. restrictive ("closed" or "negative") formulary (i.e., coverage restricted to formulary drugs except for emergencies)

iii. "restrictive with exceptions" formulary (i.e., coverage restricted to formulary but with exceptions routinely allowed)?

(b) Which of the following best describes your formulary(s) used by clients?
a. formulary is a standard, PBM designed and maintained
b. formulary is customized, modified by the PBM to meet client needs
c. formulary is customized, modified by the client and implemented/maintained by the PBM

i. What percentage of your covered lives use a PBM-designed formulary (i.e., PBM selects drugs)?

ii. What percentage of your covered lives use client-tailored formularies (i.e., PBM offers P&T support, new product analysis, etc.)?

(c) Does the type of formulary tend to differ by client type (i.e., employer vs. insurer vs. HMO)? If so, how? (Open/closed, Standardized/custom)

(d) ~~omit~~

(e) How often are changes made to the formularies?

(f) How are "new" drugs added?

(g) What mechanisms do you use to implement the formulary?
What incentives do you create for the physician?
. . . the patient?
. . . the pharmacist?

Probe for: Differential co-payment to patient, payment of difference co-pay between brand name and generic, incentive payment to prescriber for formulary compliance, incentive payment to pharmacists for formulary compliance, generic dispensing, patient pays the difference between generic and brand name, whether the formulary is motivated by manufacturer rebates, prescribing of OTCs, no prescribing.

(h) What mechanism does a patient or a physician have with the PBM to gain access to a non-covered drug?

Do you have a mechanism (e.g., Prior Authorization) to get these drugs paid for in individual instances? What is it?

What control do you have over the P&T committee(s)?

B. Pharmacy Panel

(a) Describe the network(s)/ panel(s).
How many pharmacies are included?
How many are actively serving clients?
How many prescriptions are dispensed in/through panel pharmacies for covered beneficiaries?

(b) Do you engage in selective contracting with community pharmacies?
Probe for contracts with chains.

(c) Are there any restrictions on choosing your pharmacy network (single chain, limited number)?

Do "any willing provider" laws in states limit your flexibility with the panel? How?

(d) What is the geographical distribution of your pharmacy network?

Typically, are they accessible to the inner city?
. . . to rural areas?

(e) How often are changes made in the network, and what criteria are used to determine the changes?

Can a pharmacy be dropped for noncompliance with resource use guidelines? (Has this happened?) Can a pharmacy re-enter the network after it has been dropped?

(f) Do you have a network that is performance-based?
Do you credential the network pharmacies?
If so, what does this involve?

(g) What are the standards of participation for the network?

If you select pharmacies based on services offered, what services are you looking for?

(h) What incentives, if any, are pharmacies given for participating in the network?

(i) Does the PBM offer the pharmacy network on-line adjudication? What is the effect--are the on-line methods more cost-effective? If you save money, to whom do the savings accrue--the PBM or the client?

C. Drug Benefit Structure/Description

Describe the structure of the drug benefit you provide. Which of the following are included in "standard/typical" benefit programs, "low services" programs, and "high services" programs?

Which ones do clients utilize most frequently (estimate proportion of clients using)?

Probes

(a) Co-payments?
(b) Deductibles?
(c) Cap on number of prescriptions per month?
(d) Cap on total dollars for drugs per year?
(e) Cap on total dollars for a single prescription?
(f) Prior authorization? Which drugs? Any dollar limit?
(g) Limits on quantity of drugs per prescription?
(h) Requirements for minimum quantity of drugs per prescription?
(i) Patient incentives for certain behavior (e.g., lesser co-payments for generic drugs than for branded products)?
(j) Do you cover/reimburse for OTC products? For what proportion of

covered lives are such provisions included in the benefit plans?

D. Mail Order (size/scope of use)

(a) Do you provide mail order dispensing?
Is it provided via in-house facilities or via an outside vendor/subcontractor?
What is the total number of covered prescriptions dispensed via mail order?

(b) What proportion of prescriptions are dispensed through mail order? (or, what proportion of covered lives are represented as mail order covered lives?)

(c) Are there incentives for patients to use mail order?
Explain/elaborate.

E. Retro- and Pro-DUR

1. Retrospective DUR

(a) Do you provide R-DUR? Is this an in-house function or do you have an outside subcontractor?

(b) Do you maintain a centralized database for use with R-DUR? (e.g. database including both retail and mail order prescriptions)

(c) Do you profile physicians?
. . . pharmacists?
What measures do you adopt, if any, to handle outliers?

(d) Do you conduct patient-level interventions?

(e) What intervention(s) is implemented?

2. Prospective DUR

(a) Do you provide on-line P-DUR? Is this an in-house function or do you have an outside subcontractor? (Who is subcontractor?)
Probe for pharmacy point-of-sale message vs. phone calls to physicians.

i. What percent of covered lives (or Rxs) are covered/reviewed with:

on-line P-DUR?

on-line claims adjudication?

ii. Does the P-DUR allow on-line access to other databases for clinical decision making?

(b) Do you include both mail order and other dispensers in one centralized database? Describe.

(c) Do you collect data on the number/percentage of DUR interventions resulting in the addition/elimination/ modification of a prescription? (e.g., What percentage of calls made to physicians for averting potentially serious drug-drug interactions result in changes in prescribing decisions in the desired direction?)

What happens to those data? Would you be willing to share such data with us? (Probe for one specific example... denial of payments for early refills? Can they give any details or results of examining this?)

3. DUR Results

(a) Do you measure results of your P-DUR or R-DUR programs?
Do you apply process standards such as:

i. Number of duplicate therapy problems or long-acting benzodiazepines for the elderly averted?

ii. Number of early refills cases denied (or reversed)?

(b) Do you measure R-DUR results by the patient or the provider?

(c) Do you evaluate underutilization? If so, how? In which areas?

F. Therapeutic Interchange Programs

(Note: these questions might be appropriate for both therapeutic and generic interchanges)

(a) Therapeutic substitution programs: Pharmacists may substitute formulary or preferred drugs for single source products (e.g., nazitidine on-formulary for ranitidine that has been removed from the formulary).

Do you have a therapeutic substitution program?
For what proportion of covered lives are such provisions included in the benefit plans?

How does your PBM assess effectiveness of this program?
What is the success of this program?
Can you provide us with any data?
Can you compare success rates for cost-based switch vs. therapeutic switch?

(b) "Switch campaigns" directed at physicians, e.g., asking to substitute a lower-cost drug when both are on formulary. May involve therapeutic (and generic?) substitution. Do you have such programs? For what proportion of covered lives are such provisions included in the benefit plans? How do you measure effectiveness of this program? What is its success? Can you provide us with any data?

(c) What incentives (if any) do you have for preferred interchanges? Describe such incentives for:
-- physicians
-- pharmacists
-- patients

(d) Do you have results from therapeutic substitution programs? Specifically, do you collect information on the number of prescriptions switched? *[Probe to clarify how this is counted; all scripts following the initial switch versus just the switch, and whether this included generic substitutions as well as therapeutic interchanges.]*

Also probe for whether this occurs: (a) for retail sales, (b) in mail programs, (c) open vs. closed formulary, (d) other.

G. Disease management programs

(a) Do you have disease management programs in operation?

What percentage of your covered lives are covered by disease management programs?

(b) What interventions are carried out through your disease management programs?

Probes:
- education of patients about proper monitoring and use of dosage form (e.g., inhalers)
- contacts with patients to encourage compliance
- contacts with providers to notify of compliance problems
- newsletters targeted at physicians
- newsletters to educate patients about self-management and/or create

demand for formulary drugs

(c) Who carries out the interventions?

(d) Do you target diseases? How many? Which ones?
e.g., asthma, diabetes, depression

(e) How, if at all, do you assess effectiveness?

(f) Can you describe an innovative aspect of your disease management program(s)?

(g) Is your disease management program coordinated with the basic health plan? In what ways? Do you have access to medical data? On what basis? How do you coordinate services with health plans that also have disease management programs?

(h) Are you also doing case management? If so, how does it differ from the disease management programs?

(i) What are the problems you are encountering in moving into disease management?

H. Cognitive Services Payment

Need a definition of cognitive services so we know PBMs are defining it in the same way.

(a) Do you reimburse pharmacists for cognitive services?

(b) For which services are you reimbursing pharmacists?
How do you determine whether cognitive services have been provided?

(c) What is the most reimbursement a pharmacist will receive for the provision of a cognitive service? (Which service?)

(d) How do you measure the effectiveness of these programs?

III. Finance

A. Costs for Drugs/Marketbasket of Drugs

Marketbasket:
a. Histamine-2 Receptor antagonists

b. Nonsteroidal antiinflammatory drugs
c. Antidepressants
d. Oral Contraceptives
e. ACE inhibitors
f. Cholesterol reducers
g. Cephalosporins
h. Calcium Antagonists

All Drugs:

Information for each category of drugs:

- PMPM cost
- Average cost per prescription
- Percent of prescriptions dispensed as generic
- Average days supply for market basket drugs
- Average prescription size (quantity dispensed)

For each of the drug categories above, please provide the information for the following client categories:

(1) a client who only use a minimum of services (e.g. only claims processing)
(2) a client using an "average" or typical level of services
(3) a client using most/many PBM service, and, if applicable,
(4) a Medicaid client

note: these service levels are defined by interviewees earlier in the Background, section C

B. Changes in Cost PMPM

Describe recent trends in PMPM costs.

Approximate growth rate for past year/several years.

What has caused the changes in PMPM costs?

C. Contracts/Rebates

(a) Do you have contracts/agreements/arrangements with manufacturers for rebates? Other price concessions (discounts)?

Are your contracts direct contracts with manufacturers? If not, with whom do you contract?

(b) How are the rebates (or discounts) arranged?

Are they based on volume or market share?

What percent of rebate contracts are based on units (volume) vs. market share?

What percent of rebate $ is based on units vs. market share?

Are rebates related to carrying a complete product line? Other?

What % of your drug spend is rebate?

Probes:

i. length of agreement/contract
ii. level of rebate/discount (ranges of rebates, typical, high, low and proportions of rebates at these levels)
iii. for single-source or multi-source products (and proportions)
iv. linked to formulary or coverage parameters (exclusive or preferred product status) and proportions of these
v. are they bundled, for product lines, or individual products (proportions of these)

(c) What proportion of manufacturers provide rebates/discounts?

To what percentage of claims are rebates/discounts applied?

What % of brand products are rebated?

(d) How long after drug use do you have to wait for rebates? (3 mo., 6 mo., end of year)

(e) What do you "provide in return" for/from the rebate/discount? (use data, market share data, patient data) Probe for specific examples.

(f) How do you measure the "success" of the rebates/discounts? What has been the impact on average cost per prescription or cost PMPM? Probe

for details/specific examples.

(g) Do you use rebates as a mechanism in your pricing strategy for clients (e.g. offer rebates as part of your pric for services, explicitly or implicitly)?

(h) How do your rebates compare to Medicaid rebates?

(i) Are performance measures incorporated into rebate contracts?

(j) How are rebates structured (split between administrative/rebate)?

D. Pharmacy Payment/Reimbursement

(a) What is your most common payment formula to pharmacies? How many different reimbursement schemes do you offer? Also describe "low" and "high" reimbursement terms that are present in one/some of your plans. Approximately what percentage of providers/plans/covered lives are represented by "typical/norm," "high," or "low" payment terms?

(b) Do you have Maximum allowable costs incorporated into your payment formulas? Are they based on their own or HCFA's published MACs (or another basis)? Explain

(c) How do you handle delays in billing for services by pharmacy providers? i.e., do you require timely (within 2 weeks) submission of claims?

E. PBM's Charges to Clients/Financial Arrangements

(a) What is the cost of each of the services you provide? What is the basis for your charges?

Probes:
-- administrative fee/RX
-- administrative fee per enrollee
-- PMPM charge
-- % of expenditures
-- % of rebates collected

(b) Do you accept capitation? --yes --no

What proportion of your covered lives is under capitation?

What are the risk-sharing arrangements?

-- fee-for-service
-- fully capitated *(what does this cover?)*
-- prospective budget
-- sharing savings/loss
-- other

How does capitation work?
i. for the plan?
ii. for the PBM?

(c) How, if at all, are PBM services integrated with other management techniques by the MCO (e.g., Does the MCO give the PBM information or vice-versa)?

(d) How often are there financial incentives or penalties between the PBM and the contracting MCOs? Examples?

(e) If your current MCO contracts include Medicaid recipients and/or Medicare beneficiaries, are there special contractual arrangements pertaining to these populations? (Specify.)

(f) In some contracts with HMOs, do large medical groups (e.g., Mullikin) take the pharmaceutical pmpm cap, then contract with the PBMs? If so, on what basis--sub-capitation? Fee per member per month for DUR services? Anything else?

(g) Do you guarantee your customers savings over the previous year? If yes, at what level?

F. Cost Savings Estimates

(a) Do you use historical comparisons (benchmarks) between this year and last year (e.g., cost of drugs per covered member; number of generic versus brand prescriptions)?

(b) Do you use a pool of clients for Rx comparisons?
(e.g., clients in related industries, clients with similar demographics--Medicaid AFDC)

(c) Do you compare your program with MCOs, fee-for-service?

(d) Do you have another method? (Specify.)

(e) What have been your estimated savings? Can you share them with us (and

specifics related to the estimates)?

What proportion of your savings derives from clinical management programs?
How much do you save based on discounted networks?
How much do you save based on C-DUR?
How much do you save based on formulary?

IV. Quality Aspects: Patient Outcomes

Assessment of Pharmaceutical Therapy Using Clinical Outcomes

(a) Do you assess "intermediate" patient outcomes (e.g., laboratory results: lipid levels for those on Mevacor; thyroid stimulating hormone for synthroid; glycohemoglobin for diabetics) or other physiological measurements (e.g., blood pressure control for hypertensives)?

(b) Do you (or your clients) measure decreased emergency department visits or hospitalizations due to any diseases? Which ones?

(c) What other measures do you use?

(d) Will you be willing to share results with us?

For each outcome that is evaluated ask:

(i) How often the assessment is made (on an as-needed basis, irregularly, or regularly);

(ii) Is the assessment targeted to specific patients/drugs?

Probes:
- all patients vs. high-risk patients (specify)
- all drugs vs. high risk drugs (specify) vs. high volume drugs (specify)

Measurement of Patient Quality of Life or Satisfaction Measures as a Result of Drug Therapy

(a) Do you use questionnaires like the SF-36? How often?

Which instruments do you use and why?

(b) Do you assess patient satisfaction? Are there any special measures used?

(c) Do you assess other service outcomes such as:

(i) If there is a mail order, how long are patients kept waiting on the telephone? How long it takes patients to receive their drugs? Extent to which patients use and are satisfied with the telephone "hot line"? Patients' satisfaction with condition of drugs upon arrival?

ii) Whether patients have adequate access to pharmacies (those of their choice).

(iii) Patient perspectives of the quality of care they receive.

For each outcome that is evaluated ask:

(i) How often the assessment is made (on an as-needed basis, irregularly, or regularly);

(ii) Is the assessment targeted to specific patients/drugs?

Probes:
- all patients vs. high-risk patients (specify)
- all drugs vs. high risk drugs (specify) vs. high volume drugs (specify)

Data Sources

If you measure intermediate or long-term outcomes, where do you obtain data:
(a) chart review?
(b) computerized claims database?
(c) computerized clinical database?

V. Legal Aspects

A. Confidentiality Issues

(a) What are the PBM's responsibilities to the client to report individual patients with high pharmaceutical expenditures (outlier patients)? Provider outliers?

(b) Are there concerns about the PBM selling patient lists to others? Allowing non-insurers access to patient information?

(c) Are there issues about the PBM selling information about drug use patterns to others (e.g., does the PBM sell market share information about H2RAs)?

(d) How do you deal with these concerns?

VI. Strategy and Future Predictions

1. How has the PBM market changed in the past five years?

2. What factors have driven the change?

3. Several large PBMs dominate the market right now. Is there likely to be more consolidation?

4. What is your market strategy, niche, or comparative advantage over competitors? What is your competitive differentiation?

What is the focus of your competitive strategy today? **(Ask first as an open-ended question, then have them rank order the top 4 or 5 items.)**

(a) volume
(b) price
(c) community pharmacy motivation
(d) integrated database
(e) disease management program
(f) mail order business
(g) formulary management
(h) generic or therapeutic substitution
(i) strategic alliances *(with whom?)*
(j) purchasing of physician group practices
(k) manufacturers rebates
(l) purchasing of medical information systems
(m) purchasing of HMOs
(n) expanding range of services
(o) target drug programs
(p) other (describe)_____

5. Are there issues from the FTC's ruling on the Eli Lilly-PCS merger that will affect your usual and customary practices?

VII. Open-Ended Questions

1. When you show a potential client your marketing information, what do you believe is the single most effective piece of information?

   How do you demonstrate value (savings) to the potential client?

2. If your PBM could completely control a drug program, what would you do to further lower costs?

3. If your PBM could completely control a drug program and had access to any patient information, what would you do to improve quality of care and/or lower costs?

4. In your five-year business plan, what are the most important challenges your company faces?

5. It has been argued that a PBM contracting directly with a State, employer, or HMO would be yet another "carve-out" that discourages integration/continuity of care and measurement of patient outcomes. How do you respond to these concerns?

6. What are your thoughts related to how your PBM balances quality and cost? Any special efforts? Assessment of success, etc.

Appendix B
PBM Listing with Data Source

Name	Address	City	State	Zip	Phone	MHC Lives	BI Lives	Rx/year	Pharmacies	PBM Est.	Source
Abbey Pharmacy Network	350 N. Lantana Suite 61	Camarillo	CA	93010	805-388-2811	25000		100000			MHC
Advance ParadigM Inc	545 E John Carpenter Fw	Irving	TX	75062	214-830-6199	9000000		50000000			MHC, APHA
Aetna Pharmacy Management	151 Farmington Ave.	Hartford	CT	06156	203-636-7050	4800000	4663417	14000000	3800	1985	MHC, BI
Allscrips Pharmaceuticals Inc.	1033 Butterfield Rd	Vernon Hills	IL	60061	800-654-0889	1000000		7000000	200	1986	MHC, BI
Alta-Rx First Health	363 N. Sam Houston Pwy	Houston	TX	77060	713-445-2582	10000000		80000000			MHC
AmeriKind Pharmacy Network	3100 W. Big Beaver Rd.	Troy	MI	48084	800-321-0103			55000000			MHC
APB America	4015 W. Lake Creek Dr.	Jackson Hole	WY	83001	301-733-9470				18000	1994	MHC, BI
Apollo Enterprises	2235 Otto Center Dr.	Glendura	CA	91740							APHA
ARAZ Group	8500 Normandale Lake	Bloomington	MN	55437	612-896-0376	245000					MHC
Argus Health Systems, Inc	715 Hereford Dr.	Kansas City	MO	64105	816-435-5420	30000000	0	150000000			MHC
Associated Prescription Services	281 Lord Baltimore Dr.	Baltimore	MD	21244							APHA
Benecard Services Inc.	118 W. State St.	Trenton	NJ	08608	201-890-7266						MHC
BeneScript Services Inc.	3300 Holcomb Bridge Rd.	Norcross	GA	30092	404-448-4344	150000		750000			MHC
Caremark Prescription Service	111 Barclay Blvd.	Lincolnshire	IL	60069	708-634-7600	15000000	14000000		53750	1985	MHC, BI, APHA
Certifax Pharmacy Services	9775 SW Gemini Dr.	Beaverton	OR	97005	800-635-3070	650000	450000	250000		1989	MHC, BI
Choice Drug Systems Inc.	2930 Washington Blvd.	Baltimore	MD	21230	800-766-2761	114325	250000	1524440	11	1984	MHC, BI
Claimspro Health Claims Svcs	24370 Nwestern Hwy	Southfield	MI	48075	810-352-2852	350000	350000		37000	1987	BI
Clinical Pharmacy Advantage	5701 Green Valley Drive	Minneapolis	MN	55437	612-820-3500						APHA
Complete Pharmacy Network	3637 Medina Rd.	Medina	OH	44256							APHA
Consultec Inc.	9040 Roswell Rd.	Atlanta	GA	30350	770-594-7799	2000000		20000000			MHC
Continental Managed Pharmacy Svs	1400 E. Schaaf Rd.	Cleveland	OH	44131	800-677-4323	500000		400000			MHC, APHA
Curaflex Prescription Services	4955 F Street	Omaha	NE	68117	800-798-1109	1200000					MHC
Cystic Fibrosis Services Inc	6931 Arlington Rd. T-200	Bethesda	MD	20814	800-541-4959	7000		80000			MHC
Diversified Pharmaceutical Svc	7760 Frances Ave	Edina	MN	55435	612-820-7000	26000000	14000000	100000000	43000	1976	MHC, BI, APHA
Diversified Prescription Delivery	206 Welch Rd.	Horsham	PA	19044	800-441-8976	300000		1000000	32000	1963	MHC, BI, APHA
Eagle Managed Care	431 Railroad Ave.	Shiremanstown	PA	17011	717-730-8300	1500000		6000000			MHC, APHA
Eckerd Health Services	8333 Bryan Dairy Rd.	Largo	FL	34647	813-399-6022	300000		1700000	34000	1995	MHC, BI
Express Scripts Inc.	14000 Riverport Dr.	St Louis	MO	63043	800-332-5455	8600000		30000000	37000	1986	MHC, BI

FFI Rx Managed Care	3502 Henderson Blvd.	Tampa	FL	33609	813-875-8662	500000		1000000			MHC
FFI Rx Managed Care Inc	8536 Crow Dr. Suite 105	Macedonia	OH	44056	216-467-9898	500000	600000	3000000	22000	1993	MHC, BI
First Health Services Corp	4300 Cox Rd.	Glen Allen	VA	23060	804-965-7400	10000000		76331000			MHC, APHA
General Computer Corp	2045 Midway Dr.	Twinsburg	OH	44087	216-425-3241	3500000	3703828	20000000	40000	1989	MHC, BI
General Prescription Programs	127 E. 59 St.	New York	NY	10022	800-341-2234	1200000		3866000			MHC
Home Pharmacy	820 W. Jackson Blvd.	Chicago	IL	60607	312-258-5244	1500000	2000000	650000	37000	1983	MHC, BI
Indpnt. Pharmaceutical Conslts.	7 Regatta Bay Court	St Louis	MO	63367	314-561-3656		900000			1991	BI
InfoCare Rx	14800 Quorum Drive	Dallas	TX	75240	800-631-2807	300000	1500000		20000	1986	MHC, BI
Integrated Health Concepts	141 N. Civic Drive	Walnut Creek	CA	94596	510-210-6363	800000	0	500000			MHC
Integrated Pharmaceutical Svcs	3400 Data Dr.	Cordova	CA	95670	916-631-5170	10500000		18000000			MHC, APHA
Integrated Pharmacy Solutions (IPS)	1601 Abbey Place	Charlotte	NC	28209							APHA
Inteq Group Inc	1100 Centennial Blvd.	Richardson	TX	75081	800-324-7799	1000000	400000	3000000	28937	1992	MHC, BI
Kroger Mngd Prescription Drug	1014 Vine St.	Cleveland	OH	45202	513-762-4968		150000		38000	1992	BI
Longs Drug Stores	141 N. Civic Dr.	Walnut Creek	CA	94596	510-937-1170						MHC
Managed Care Rx	20 Enford Rd. PO Box 623	Lemoyne	PA	17043	717-761-0910	11000		480000			MHC
Managed Pharmacy Benefits Inc.	1100 N. Lindbergh Blvd.	St Louis	MO	63132	800-585-5051	400000		30000000			MHC
Managed Prescription Network	404 Bedshire Center	Greenburg	PA	15601	412-838-9669				32000	1988	BI
Managed Prescription Services	One City Centre Ste 110	St Louis	MO	63101	314-259-4200	5000000	3500000	30000000	33000	1984	MHC, BI
MaxorPLus	12 Medical Dr.	Amarillo	TX	79106	806-358-7955						MHC
Medi-Mail	1550 S Indiana 2nd Flr	Chicago	IL	60605	312-922-9220	500000	0	0			MHC
Medi-Mail	871-C Grier Dr.	Las Vegas	NV	89119	702-361-2422	500000	0	1200000			MHC
Medical Matrix	6300 Ridglea Pl. Ste 703	Fort Worth	TX	76111	800-880-1398	0	0	0			MHC
Medicap Pharmacy Inc.	4700 Westown Pkwy.	W. Des Moines	IA	50266	515-224-8400						MHC
MedImpact Pharmaceutical Mgt Inc.	10660 Scripps Ranch Blvd.	San Diego	CA	92131	619-566-2727	3800000		27000000			MHC, APHA
Mednet/Medi-Claim	20 Erford Rd.	Lemoyne	PA	17043	717-761-5266	2000000		3000000			MHC, APHA
Merck-Medco Managed Care	100 Summit Ave	Montvale	NJ	07645	201-358-5400	47000000	41000000	180000000	52000	1965	MHC, BI, APHA
National Data Corp	National Data Plaza	Atlanta	GA	30329	404-728-2726						MHC
National Medical Health care	26 Harbor Park Dr	Port Washington	NY	11050	516-626-0007	0	0	0			MHC
National Pharmaceutical Services	713 N. 132nd St.	Omaha	NE	68154	800-546-5677	110000	110000		20000	1990	BI
Natl Prescription Administrators	711 Ridgedale Ave.	East Hanover	NJ	07936	201-503-1000	6750000	6500000		51000	1978	MHC, BI, APHA
Northwest Pharmacy Services	11413 E. Meridian	Puyallup	WA	98371							APHA
OPN Open Pharmacy Network	369 Billy Mitchell Rd	Salt Lake City	UT	84098	801-238-6047	50000	0	0			MHC
OPTIUM Pharmacy Services	7245 Henry Clay Vlbd	Liverpool	NY	13088	315-451-8000	0	0	0			MHC

PAI	PO Box 23007	Little Rock	AR	72221	501-221-2330	800000	0	3000000			MHC
PBM- Plus	4413 Honeysuckle Court	Oshkosh	WI	54904	414-236-6036	300000		2000000			MHC
PCS Health Systems Inc.	9501 E. Shea Blvd.	Scottsdale	AZ	85260	602-391-4600	56000000	56000000	320000000	54000	1969	MHC, BI, APHA
Pequot Pharmaceutical Network	One Annie George Dr.	Mashantucket	CT	06339	203-572-1948	1100000	750000		15000	1992	MHC, BI
Perform Cost Mngt Services	9700 E 91st. Suite C 232	Scottsdale	AZ	85258							APha
Pharma-Link Inc	6330 Lamar Ave Ste 200	Overland Park	KS	66201	913-262-5920	500000	0	2000000			MHC
PharmaCare Mngt Services	25 Blackstone Valley Pl	Lincoln	RI	02865	401-334-0069	1200000		7800000			MHC
Pharmaceutical Care Network	1112 I Street Suite 100	Sacramento	CA	95814	916-558-1400						APHA
Pharmacist Service Group Inc.	570 Liberty Street	Salem	OR	97301	503-588-6660	175000		1100000			MHC
Pharmacon Consultants	PO Box 1335	Whittier	CA	90609	310-941-3931						MHC
Pharmacy Card Inc. (PCI)	135 Chesterfield	Maumee	OH	43537							APHA
Pharmacy Corp. of America	1800 38th Street	Boulder	CO	80301	800-458-3784						APHA
Pharmacy Data Management	124 S. Main St.	Poland	OH	44514							APHA
Pharmacy Gold Inc.	PO Box 64812	St Paul	MN	55164	612-456-1545	15000000	18000000	83000000	35000	1986	MHC, BI, APHA
Pharmacy Network Natl Corp	4000 Wake Forst Rd	Raleight	NC	27609	919-876-4642	250000	0	1200000			MHC
Pharmacy Network Services	PO Box 530683	Birmingham	Al	35205							APHA
Pharmacy Select Inc.	6522 Seybold Rd.	Madison	WI	53719	608-274-7732						MHC
Pharmacy Service Corp of NY	286 Washington Ave. Ext.	Albany	NY	12203	518-456-2946	1000000		6000000			MHC, APHA
Pharmacy Services Group	1100 51st St.	Fort Lauderdale	FL	33334	800-851-1000	400000		2500000			MHC
Preferred Phamacy Network	300 Capital St. #1002	Charleston	WV	25301							APHA
Prescription Mngt Services	360 W Northwest Hwy	Palatine	IL	60067	800-992-1119						MHC
Prescription Mngt Services Inc.	3611 Queen Palm Dr.	Tampa	FL	33619	800-237-7676			350000			MHC
Prescription Network of Kansas	1308 W.10th	Topeka	KS	66604	913-232-1712	23000		152000			MHC
Prescription Solutions	5701 Katella Ave.	Cypress	CA	90630	800-479-7658	4000000	3200000	3200000	30000	1989	MHC, BI, APHA
Primextra Inc.	435 Ford Rd.	Minneapolis	MN	55426	612-546-4353	350000		1500000			MHC
Priority Pharmacy	3935 First Ave.	San Diego	CA	92103	800-788-2232						MHC
Pro-Mark Holdings	25 North Rd.	Peace Dale	RI	02883							APHA
Pro-Serv	1901 Main Street	Buffalo	NY	14240	716-887-8989						APHA
ProVantage Prescription Mngt	700 Pilgrim Way	Green Bay	Wi	54307	414-496-4296	2400000		14000000			MHC
Provider Health Services	27 North Rd.	Peace Dale	RI	02883							APHA
ProxyMed Inc.	2501 Davie Rd. Suite 230	Fort Lauderdale	FL	33317	305-473-1001						MHC
Prudential Pharmacy Mngt	56 Livingston Ave.	Roseland	NJ	07068	201-716-1015	5000000		19000000			MHC
Restat	724 Elm St. P.O. Box 758	West Bend	WI	53095	800-926-5858	5000000	5000000	28000000	45000	1985	MHC, BI

Rx Management Inc.	2160 Highland Ave.	Birmingham	Al	35205	205-939-4709						APHA
RxAmerica	369 Billy Mitchell Rd.	Salt Lake City	UT	84116	801-238-6000	1600000	800000	7000000	33000	1994	MHC, BI
RXConnections	1925 Enterprise Park	Twinsburg	OH	44087	216-487-1000	4000000		73000000			MHC
RxPrime	900 Cottage Grove Rd	Hartford	CT	06152	680-726-6881	1200000					MHC, APHA
TDI Managed Care Services Inc.	620 Epsilon Dr.	Pittsburg	PA	15238	412-967-2300	11000000	11500000	3000000	40000	1982	MHC, BI
United Managed Care Inc.	7227 N 16 St Ste 160	Phoenix	AZ	85020	602-678-1179	1300000					MHC
United Provider Services	5125 Davis Blvd	Fort Worth	TX	76180	817-281-8820	215000	0	1400000			MHC
Universal RX	3601 Thirlando Rd NW	Roanoke	VA	24109	800-966-8393	535000	0	2910000			MHC
Valu-Script	1 Golf View Dr	Altoona	PA	16601							APHA
ValueRx	4700 Nathan Lane North	Plymouth	MN	55442	612-509-2500	27000000	16000000	56000000	42000	1985	MHC, BI, APHA
Wal-Mart Stores Inc.	702 SW Eighth St.	Bentonville	AR	72716	501-273-6744	1000000					MHC
Wellpoint Pharmacy Management	27001 Agoura Rd. #325	Calabasas Hills	CA	91301	818-878-2644	10000000		58000000			MHC, APHA
WHP Health Initiatives, Inc	520 Lake Cool Rd	Deerfield	IL	60015	847-374-2640	1800000	0	0			MHC

APPENDIX C

Sample PBM Panel Description

	Available Pharmacies	Network I	Network II	Exclusive Provider Network
Mileage Range	**Percent of Population Within Range**	**Percent of Population Within Range**	**Percent of Population Within Range**	**Percent of Population Within Range**
<1 Mile	88.7%	88.7%	86.5%	87.5%
<3 Miles	90.5%	90.5%	88.9%	89.7%
<5 Miles	92.5%	92.5%	91.1%	92.0%
<7 Miles	94.8%	94.8%	93.5%	94.4%
<10 Miles	97.4%	97.4%	96.4%	97.3%
Density				
No. of Pharmacies Nationwide	54,861	53,203	44,024	21,035
% of Pharmacies Nationwide	100%	97%	80.2%	38.3%
% of Chain Pharmacies	50.8%	52.2%	51.5%	70.1%
% of Independent Pharmacies	49.2%	47.8%	48.5%	29.9%
Network Pricing				
Brand Ingredient Cost	N/A	-12%	-13%	-15%
Generic Ingredient Cost	N/A	MAC	MAC	MAC
Dispensing Fee - Brand	N/A	$2.25	$2.00	$2.00
Dispensing Fee - Generic	N/A	$2.75	$2.50	$2.50

Appendix D
Status of Medicaid DUR Activities (FY 1994)

State*	PDUR type	ECM** Start Date	RDUR Start Date	Savings***	Evaluator
AK	On-site	1995	1993	Yes	First Health Services
AL	On-site	1996 or later	1992	Yes	Auburn U
AR	On-site	1996 or later	1984	Yes	HID
CO	On-site	1996 or later	1990	Yes	U of Colorado
CT	On-site	1996 or later	1992	Yes	HID
DE	ECM	1994	1994	No	NA
FL	On-site	1995	1982	Yes	Unisys
GA	On-site	1995	1993	No	NA
HI	On-site	No plans	1994	No	NA
IA	On-site	1996 or later	1984	Yes	Iowa Foundation
ID	On-site	1996 or later	1992	Yes	Idaho State College
IL	ECM	1993	1992	No	NA
IN	On-site	1995	1995	No	NA
KS	On-site	1996 or later	1977	Yes	First Health Services
KY	On-site	1995	1988	Yes	First Health Services
LA	On-site	1996 or later	1991	Yes	Unisys
MA	On-site	1995	1991	Yes	HID
MD	ECM	1993	1986	Yes	HID
ME	On-site	1995	1995	No	NA
MI	On-site	No plans	1985	Yes	PharMark/HID
MN	On-site	1995	1994	No	NA
MO	ECM	1992	1992	Yes	PharMark/GTE
MS	On-site	1995	1984	No	NA
NC	On-site	1996 or later	1993	Yes	First Health Services
ND	On-site	1996 or later	1992	Yes	NDPhA, Iowa Foundation
NE	On-site	1995	1983	Yes	HID
NH	On-site	1995	1993	No	NA
NJ	On-site	1996 or later	1993	No	NA
NM	ECM	1993	1992	Yes	First Health Services
NV	On-site	No plans	1993	No	NA
OR	ECM	1994	1989	Yes	First Health Services
PA	ECM	1993	1993	No	NA
RI	On-site	1995	1993	No	NA
SC	On-site	1995	1988	Yes	First Health Services
SD	On-site	No plans	1991	Yes	U of South Dakota
TX	On-site	1995	1992	No	NA
UT	On-site	1995	1992	Yes	U of Utah
VT	ECM	1993	1992	No	NA
WA	On-site	1996 or later	1991	Yes	U of Washington
WI	On-site	1996 or later	1984	Yes	U of Wisconsin
WV	ECM	1992	Not reported	No	NA
WY	On-site	1995	1993	Yes	PharMark

*(N=42) Data were not available for 8 states at the time of the study
**EMC=Electronic Claims Management
***Claims of Cost Savings for R-DUR/P-DUR

Data Source: Medicaid Annual DUR reports to HCFA

Appendix E
Medicaid Estimates of DUR Savings (FY 1994)

State*	RDUR Savings Est	Design for R-DUR studies	PDUR Savings Est**
AK	$6,513.00	pre-post	
AL	$1,149,000.00	pre-post	
AR	$3,115,185.00	pre-post	
CO	$289,055.00	Estimate-No cost data available	
CT	$1,790,000.00	pre-post	
DE			
FL	$108,000.00	Estimate-No cost data used	
GA			
HI			
IA	$1,516,299.00	pre-post	
ID			
IL			
IN			
KS	$41,118.00	pre-post	
KY	$373,668.00	pre-post	
LA	$4,377,000.00	pre-post	
MA	$3,417,596.00	pre-post	
MD			$8,900,000.00
ME			
MI	$4,319,000.00	pre-post with and without control	
MN			
MO	$41,947.00	pre-post	$793,000.00
MS			
NC	$32,000.00	pre-post	
ND	$54,086.00	pre-post	
NE	$75,536.00	pre-post	
NH			
NJ			
NM			$1,543,039.00
NV			
OR	$35,455.00	Unknown	$167,248.00
PA			
RI			
SC	$78,772.00	pre-post	
SD	$46,355.00	pre-post	
TX			
UT	$422,998.00	pre-post	
VT			
WA	$12,402.00	pre-post with control	
WI	$73,000.00	pre-post with control	
WV			
WY	$62,747.00	pre-post	

*(N=42) Data were not available from 8 states at the time of the study
** P-DUR study design not reported for NM, OR, PA; MD claimed savings for denials and reversals

Date Source: Medicaid Annual DUR Reports to HCFA